

EXHIBIT 41

Page 1

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DORIEN SATO, CSR 12508, CER

Page 2

Page 3

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation,) MDL No. 15-2666) (JNE/FLN))

Videotaped deposition of JONATHAN SAMET, M.D., taken on behalf of Defendants, at 601 South Figueroa Street, Suite 2500, Los Angeles, California 90071, commencing at 10:57 a.m., Tuesday, July 11, 2017, before Dorien Saito, CSR 12568, CLR.

APPEARANCES

FOR PLAINTIFFS:

CIRESI CONLIN
By: JAN CONLIN, ESQ.
225 South 6th Street
Minneapolis, Minnesota 55402

FOR DEFENDANTS:
BLACKWELL BURKE
By: COREY GORDON, ESQ.
431 South Seventh Street
Minneapolis, Minnesota 55415

ALSO PRESENT:

JORDAN LEADS, Videographer
JONATHAN BORAK
MORDECAI BOONE

Page 4

Page 5

INDEX

WITNESS:

	PAGE
JONATHAN SAMET, M.D.	
EXAMINATION BY MR. GORDON	8
AFTERNOON SESSION:	
EXAMINATION BY MR. GORDON	97

INFORMATION REQUESTED:
(NONE)

QUESTIONS INSTRUCTED NOT TO ANSWER:
(NONE)

EXHIBITS:

EXHIBITS	NUMBER	DESCRIPTION	PAGE
Exhibit 1		Expert report of Jonathan M. Samet M.D., M.S. dated March 30, 2017	28
Exhibit 2		Article entitled "Arthroplasty, Forced-air warming and ultra-clean ventilation do not mix"	61
Exhibit 3		Expert Report of Theodore R. Holford, Ph.D.	71
Exhibit 4		Publication from the CDC regarding the health consequences of smoking	84
Exhibit 5		Raw case data (No infection or infection)	128

EXHIBITS:		
NUMBER	DESCRIPTION	PAGE
Exhibit 6	Article entitled "Arthroplasty, Forced-air warming and ultra-clean ventilation do not mix"	129
Exhibit 7	Email from Mark Albrecht to Mike Reed, et al. With cc to Scott Augustine dated January 31, 2011	132
Exhibit 8	Email from Mark Albrecht to Mike Reed with cc to Scott Augustine dated November 1, 2010	136
Exhibit 9	Spreadsheet	137
Exhibit 10	Document entitled "Implementing effective SSI surveillance"	14
Exhibit 11	Trust Wide Surgical Site Infection Intervention Timeline for Orthopaedic THR & TKR surgery (including revision) and Repair Neck of Femur	142
Exhibit 12	Email from Mar Albrecht to Mike Reed and cc to Christopher Nachtshem dated November 22, 2011	149
Exhibit 13	Document entitled "A Novel Approach to Assess the Effect of a Forced-air Patient Warming System on Increasing the Risk of Nosocomial Infections at the Surgical Wound Site" by Farhad Memarzadeh, Ph.D., P.E.	169

Page 6

Page 7

EXHIBITS:		I N D E X (continued)
NUMBER	DESCRIPTION	PAGE
Exhibit 14	Article entitled "Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance" by Kumar G. Belani, Mark Albrecht, Paul McGovern and Christopher Nachtsheim, Ph.D.	182
Exhibit 15	Article entitled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room" by Mark Albrecht, Robert L. Gauthier, M.D., Kumar Belani, Mark Litchy, M.E. and David Leaper, M.D.	184
Exhibit 16	Article entitled "Arthroplasty, Do forced air patient-warming devices disrupt unidirectional downward airflow? By A.J. Legg, T. Cannon and A.J. Hamer	186
Exhibit 17	Article entitled "Arthroplasty, Forced-air patient warming blankets disrupt unidirectional airflow" by A.J. Legg and A.J. Hamer	188
Exhibit 18	Email from Mark Albrecht to Andrew Legg, M.D., Scott Augustine and Christopher Nachtsheim dated September 10, 2010	189
Exhibit 19	Email from Mark Albrecht to Mike Reed and Paul McGovern dated July 9, 2010	191

LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

10:57 A.M.

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THE VIDEOGRAPHER: This is the start of tape labelled Number 1 of the videotaped deposition of Dr. Jonathan Samet in re Bair Hugger Forced Air Warming Products Liability Litigation in the United States District Court, District of Minnesota, Case Number 15-2666(JNE/FLN).

This deposition is being held at 601 South Figueroa Street, Suite 2500, Los Angeles, California, on Tuesday, July 11 of 2017 at approximately 10:58 a.m.

My name is Jordan Leads from TSG Reporting, Incorporated, and I'm the legal video specialist.

The court reporter is Dorien Saito in association with TSG Reporting.

Will counsel please introduce yourselves.

MR. GORDON: Corey Gordon on behalf of the defendants 3M Alizant. Also with me today is Mordecai Boone, the in-house counsel #M as well as Professor Jonathan Borak, experts.

MS. CONLIN: Jan Conlin and Mike Sacchet

Page 8

Page 9

1 on behalf of the plaintiffs from Ciresi Conlin.
2 THE VIDEOGRAPHER: Thank you.
3 THE REPORTER: Would you raise your right
4 hand.
5 THE WITNESS: (Complies.)
6 THE REPORTER: Do you so state under
7 penalty of perjury that the testimony you shall
8 give in your deposition shall be the truth, the
9 whole truth, and nothing but the truth?
10 THE WITNESS: Yes, I do.
11 ***
12 JONATHAN SAMET, M.D.,
13 having been duly administered an oath
14 in accordance with CCP 2094, was
15 examined and testified as follows:
16 ***
17 EXAMINATION
18 BY MR. GORDON:
19 Q Good morning, Dr. Samet.
20 A Good morning.
21 Q As you know from our brief introduction a
22 moment ago, my name is Corey Gordon. And I'll be
23 asking you some questions today about the expert
24 opinions you proffered in the multidistrict litigation
25 pending.

So you've had your deposition taken several times before; is that correct?

A I have in the past, yes.

Q And you've testified as an expert witness in litigation before; is that correct?

A That's correct.

Q Now, I know you've testified as an expert in several cases involving the claims being made against the tobacco industry.

Is that correct?

A That's correct.

Q Have you testified as an expert or offered -- well, strike that.

Have you testified as an expert in any cases involving anything other than tobacco-related claims?

A To my recollection, solely tobacco.

Q And have you offered opinions maybe that didn't lead to you ever having to give a deposition or testimony in court outside of the tobacco arena?

A I would suspect if I looked back across a long career, I've had lawyers contact me about a variety of matters. At most these resulted in conversations but nothing further.

Q I'm guessing that you've probably been frequently asked by lawyers to serve as a consultant

Page 10

1 testifying for a witness.

2 Is that true?

3 A It seems to happen from time to time.

4 Q And I'm guessing you probably end up saying
5 no a lot more than you say yes.

6 Right?

7 A In general, that would be true, yes.

8 Q How did you come to be involved in this
9 litigation?

10 A In this case, I was approached by
11 Michael Ciresi and Jan Conlin and asked if I would
12 review the materials related to Bair Hugger and
13 consider being an expert witness.

14 Q And you had worked with Mr. Ciresi in
15 connection with the Minnesota tobacco litigation; is
16 that correct?

17 A That's correct.

18 Q Was that your first experience as an expert
19 witness, the Minnesota tobacco litigation?

20 A Probably not. Reaching back in my career, I
21 at least worked with a group of lawyers in San Antonio
22 early in my career, an issue related to asbestos in
23 the renovation of the hotel. But that was probably in
24 the early eighties somewhere.

25 Q Did that ever result in you giving testimony?

Page 12

1 so I agreed to do it.

2 Q Okay. And I take it that you're -- you know,
3 you developed a relationship with Mr. Ciresi and
4 Ms. Conlin over the years such that you have --
5 consider them friends.

6 Is that fair?

7 A Well, I've known Michael Ciresi since the
8 Minnesota litigation, and I've worked with the firm
9 for four years in preparation for the case, so I
10 certainly knew Michael Ciresi well. I met Jan Conlin
11 more recently.

12 Q If memory serves me correctly, Tom Hamlin was
13 also heavily involved with preparing you?

14 A I worked closely with Tom Hamlin. He was
15 sort of the -- I guess the person who put -- was
16 the -- was the lead on damages estimation and some of
17 the health-related issues.

18 Q In this litigation, the Bair Hugger district
19 litigation, what -- what is the expertise that you are
20 offering to the court? How would you characterize it?

21 A I -- I guess I would characterize it at
22 several levels.

23 One, I'm not a surgeon, but I have a medical
24 background and -- and did spend two years doing
25 anesthesia.

Page 11

1 A As I recall, the case was settled out of --
2 out of court.

3 Q Before you would have been deposed.

4 Other than that asbestos case, though, I
5 thought I had read something you had written that led
6 me to believe that the Minnesota tobacco litigation
7 was the first time that you -- maybe the first time
8 you testified in court.

9 Does that sound right?

10 A Correct.

11 Q Okay. And have you -- in the
12 intervening years, about twenty years, have you done
13 any work with the -- Mr. Ciresi or his partners?

14 A I have not worked with him directly. I've
15 been in touch -- in touch with him from time to time
16 mostly -- mostly saying hello and other things. I
17 remained friends with one of the lawyers from the
18 Minnesota tobacco case.

19 Q What -- so what was it about this case that
20 prompted you to venture outside the tobacco arena for
21 expert testimony?

22 A I guess probably two reasons. One was the --
23 a request from Michael Ciresi and Jan Conlin. Second
24 was the -- you know, my -- my initial understanding on
25 books that -- the specifics of the case. And so I --

Page 13

1 Second, I've, of course, trained in
2 epidemiology and have put a lot of thought over
3 the years into how one makes judgments about -- about
4 evidence.

5 Third, I have a great deal of experience
6 around issues related to airborne particles, some --
7 some understanding of ventilation issues particularly
8 coming out of my work with tobacco and serving on
9 ASHRAE Committee 62. So I worked on a number of
10 issues related to airborne particles.

11 Q Okay. So I want to talk about those three
12 different buckets. I'll call the middle -- middle
13 bucket epidemiology. We'll put that aside. I want to
14 understand better your -- the expertise that you are
15 proffering in the other areas.

16 You -- you said you're not a surgeon, but
17 you've done anesthesia for two --

18 Was it two years?

19 A That's correct.

20 Q How long ago was that?

21 A Oh, quite a while ago. As I said in my
22 report, I was in the Army from '71 to '73 and was made
23 an anesthesiologist after on-the-job training for
24 anesthesiology.

25 Q Do you consider yourself an expert in

1 anesthesiology?

2 A Not based on two years of experience. But I
3 certainly regard myself as familiar with the operating
4 room setting.

5 Q When was the last time you were in an
6 operating room?

7 A I'm not sure, frankly. Probably at some
8 point during my clinical career.

9 Q And what would the time parameters be for
10 your clinical career?

11 A It extended through 1994.

12 Q Would you say that you are -- strike that.

13 If there had been any changes in surgical --
14 surgical procedures or operating room design or
15 technique issues since 1994, do you -- do you have any
16 reason to think you would have expertise in -- in
17 post-1994 issues?

18 A Certainly I've made no effort to track what
19 is going on in terms of operating room technology or
20 approaches.

21 Q And what I'm trying to do is -- is understand
22 the scope of -- of your -- of where your expertise is.
23 I think I have a pretty good idea of what your
24 epidemiology and expertise is, but I want to
25 understand where -- you know, what these other areas

1 are.

2 You're not claiming expertise in
3 microbiology, are you?

4 A I'm certainly familiar with clinical
5 infections, but I'm not a trend microbiologist.

6 Q What does it mean to be familiar with
7 clinical infections?

8 A Well, in a many year career in pulmonary
9 medical and general internal medicine, I certainly saw
10 many people with a variety of infections.

11 Q Do you know the -- for example, the size of
12 various bacteria?

13 A Oh, I have some general idea of the
14 aerodynamic diameter of bacteria, yes.

15 Q Okay. Let's take staph bacteria.

16 What -- what would be the aerodynamic size of
17 a single staph bacteria or the range, the size range?

18 A I'm not -- I can't say that I can sit here
19 today and for each species give you a range of
20 aerodynamic diameter. It's in the range of submicron
21 and up depending on bacteria form of species.

22 Q Okay. Would you -- do you consider yourself
23 an expert in nosocomial infections?

24 A Not specifically, no.

25 Q How about more broadly, just infectious

1 diseases?

2 A Again, I -- I will just say that as -- as
3 part of my general background, I have both clinical
4 experience in pulmonary medicine, critical care
5 medicine. I take care of many people with infections.

6 And while at Johns Hopkins, my department
7 included one of the world's larger groups of
8 infectious disease epidemiologists, so I had an
9 opportunity to learn something from them.

10 Q Have you done any epidemiology work in
11 connection with specific infectious processes?

12 A Oh, I have a few papers on my CV related,
13 actually, but it's certainly not related to this.

14 Q Let's talk about what the major focus has
15 been. One -- one focus has been cancer; right?

16 A I'm sorry. Of my work?

17 Q Of your -- your professional work.

18 A One has been cancer, correct.

19 Q Other would be -- another bigger would be
20 other lung diseases such asthma, COPD, in that --

21 A Well, certainly those would be included as --
22 as well. And I would add environmental pollutants
23 above -- indoors and outdoors as a critical focus and
24 also cardiovascular disease and sleep.

25 Q Sleep apnea?

1 A Sleep apnea.

2 Q And, again, are there -- are there infectious
3 agents that cause cancer?

4 A Yes.

5 Q Have -- have you done any work in --
6 specifically in infectious agents in cancer?

7 A I've published on hepatitis B virus and liver
8 cancer in my career.

9 Q And in the -- okay. And I'm just -- again,
10 I'm trying to understand, you know, your professional
11 activities and how they would relate to infection as
12 opposed to other disease processes -- processes that
13 result in cancer or most cancers or asthma or cardiac
14 conditions.

15 As you sit here now, can you think of any
16 other peak area of -- of work in your professional
17 career in last twenty or thirty years that you would
18 characterize as being related to infection?

19 A Some papers related to tuberculosis, along
20 with hepatitis B virus work.

21 Q Is hepatitis B and tuberculosis would be the
22 main --

23 A Among -- among the topics that I published,
24 yeah.

25 Q Have you done any work in the -- specifically

1 in the area of surgical site infections?
 2 A No, I have not.
 3 Q And I'll ask the broader question first.
 4 So I assume that means you haven't done any
 5 professional work in the area of prosthetic joint
 6 infections?
 7 A No, not specifically.
 8 Q And you don't -- I'm not asking to insult
 9 you. I'm asking just to kind of close the doors on
 10 the areas that I'm assuming I don't have to spend a
 11 lot of time on.
 12 You don't consider yourself an expert in
 13 orthopedics; correct?
 14 A No.
 15 Q You don't consider yourself an expert in
 16 mechanical engineering specifically with respect to
 17 HVAC systems; correct?
 18 A I don't consider myself an expert, but I
 19 did -- I will just repeat it. I did serve on ASHRAE
 20 Committee 62, which is a ventilation standards
 21 committee.
 22 Q Let's talk about that because I was -- I put
 23 that in Bucket 3 anyhow too.
 24 So the -- the work that you did on ASHRAE 62,
 25 what -- what did that involve?

1 could potentially impact indoor air quality; correct?
 2 A Certainly. Tobacco smoking has been a key
 3 source of indoor air pollution.
 4 Q And particulate matter in certain size ranges
 5 is -- can be considered something that can degrade
 6 indoor air quality; correct?
 7 A Well, certainly particles generally -- I
 8 mean, that's a very broad umbrella term -- are among
 9 the indoor pollutants of -- of concern, having many
 10 sources.
 11 Q And broadly speaking, there -- some particles
 12 are capable of causing an infectious process such as a
 13 bacterial or viral process; right?
 14 A Right.
 15 Q And there are other that particles that,
 16 although they may be potentially damaging in other
 17 ways, they don't initiate infection the way that
 18 bacteria or viruses do; correct?
 19 A Not all particles are infectious.
 20 Q And in your -- in your professional
 21 activities, your research and your publications, have
 22 you done any -- any work dealing with particulate
 23 matter that you would characterize as infectious other
 24 than the stuff we've talked about, hepatitis and
 25 tuberculosis?

1 A It involved many committee meetings and --
 2 and discussions. And, you know, it is a consensus
 3 process organization. So a variety of discussions
 4 about ventilation spaces and the amount of ventilation
 5 needed particularly in the presence of cigarette
 6 smoking.
 7 Q Would it be safe to say that the particular
 8 expertise that you brought to the ASHRAE Committee in
 9 which you served was your extensive experience in
 10 respiratory illnesses in general and secondhand smoke
 11 in specific?
 12 A Well, I -- I brought -- I brought that. I
 13 also brought the work I had done on indoor air
 14 pollution and indoor air pollution measurement and a
 15 broad background of -- from discussing these issues
 16 with colleagues over the years.
 17 I also edited the Indoor Air Quality Handbook
 18 that was published by McGraw-Hill in about 2000 that
 19 provided extensive coverage of a variety of --
 20 comprehensive coverage of issues related to air
 21 quality. It covered mechanical ventilation systems.
 22 Q When you talk about indoor air quality, I'd
 23 like to know what that encompasses.
 24 Secondhand smoke environment of tobacco
 25 smoke, that would be something that would impact --

1 A I'm sorry. Could you repeat the question.
 2 Q Let me ask -- let me approach it differently.
 3 You've done a lot of research in -- into the
 4 issues relating to both indoor and -- and
 5 environmental pollution from noninfectious agents,
 6 diesel fumes, carbon black, things like that; right?
 7 A I've studied different inhaled agents. Some
 8 are particulates, yes.
 9 Q Okay. Have you done --
 10 What -- what percentage of your work has been
 11 in -- in looking at inhaled particulates that were
 12 infectious agents?
 13 A Oh, I -- I would not say that I focused
 14 specifically on infectious agents in inhaled air.
 15 Q Well, would the converse be true, that your
 16 focus has primarily been on noninfectious agents?
 17 A Well, I -- I would say sometimes the focus
 18 has been general. I mean, that is, particles. And
 19 sometimes it's been more specific, characterized into
 20 particles in some particular way.
 21 Q Have you done any -- any -- well, take, for
 22 example, something like a SARS epidemic -- a SARS
 23 epidemic.
 24 Did you do any research that would relate to
 25 something like a SARS epidemic?

Page 22

1 A I'm not sure I know what you mean.
 2 Q Well, there are certainly epidemiologists
 3 who -- whose focus is on the transmission of
 4 infectious agents; correct?
 5 A I'm sorry. Some epidemiologists study
 6 infectious agents.
 7 Is that the question?
 8 Q Right.
 9 A Yes.
 10 Q And some study the transmission of
 11 infectious -- infectious agents through non-airborne
 12 routes; correct?
 13 A It would seem to -- I mean, certainly people
 14 study infectious agents that may be transmitted by
 15 different means and different media, if that's your
 16 question.
 17 Q And -- and there are epidemiologists who
 18 devote a significant portion of their professional
 19 activities to study airborne transmission of
 20 infectious agents; right?
 21 A Some do.
 22 Q Okay. And -- and you would not consider
 23 yourself -- you wouldn't hold yourself out as -- as
 24 that type of epidemiologist, right, one who study --
 25 who -- who devotes a substantial portion of his

Page 23

1 professional career studying specifically the
 2 transmission of airborne infectious agents?
 3 A That's not been a focus of my career
 4 specifically.
 5 Q And I -- I guess at -- has it been a focus of
 6 your career generally?
 7 MS. CONLIN: Asked and answered.
 8 THE WITNESS: I'm sorry.
 9 BY MR. GORDON:
 10 Q Well, I said you wouldn't characterize that
 11 as a focus of your career. You said not specifically.
 12 So has -- has it been a focus of your career
 13 generally.
 14 A In terms of my research specifically, no. In
 15 terms of things I read about, you know, just --
 16 For example, the SARS epidemic, I tracked
 17 very closely for a variety of reasons, including
 18 holding an advisory position with the infectious
 19 disease group in Hong Kong.
 20 So I -- I have a general interest in my field
 21 of epidemiology do I do work. Specifically research
 22 on airborne pathogens, no.
 23 Q And so when you use the term "pathogen" --
 24 A I mean, an organism that causes disease.
 25 Q So you wouldn't consider tobacco smoke to be

Page 24

1 an airborne pathogen; right?
 2 A No, I would not.
 3 Q Or diesel fumes?
 4 A In terms of causing infectious disease, no.
 5 Q What -- I'm sorry.
 6 Did you have some professional activities in
 7 advising the Hong Kong government during the SARS
 8 epidemic?
 9 A No. Following the SARS epidemic, the China
 10 University of Hong Kong established an emerging
 11 infectious disease center. I was on their advisory
 12 board for a couple of years.
 13 Q What did you do in that -- in that advisory
 14 board role?
 15 A I guess I did what people do on an advisory
 16 board. I went to meetings in Hong Kong. Mainly we
 17 discussed their research plans and what they were
 18 doing.
 19 Q Getting back to the ASHRAE 62 committee.
 20 There were various subcommittees within that; correct?
 21 A There are various subcommittees, working
 22 groups.
 23 Q And there were one or more subcommittees or
 24 working groups that were looking specifically at
 25 hospital HVAC systems; right?

Page 25

1 A Actually, the group I was on was concerned
 2 with -- was not concerned specifically with hospital
 3 systems.
 4 Q Okay. It saves some time. Thanks.
 5 So your actual work really didn't involve
 6 hospital HVAC systems?
 7 A It involved commercial buildings, but not
 8 hospital HVAC systems.
 9 Q And, again, the focus there would be on
 10 general air quality, not control of airborne pathogens
 11 specifically?
 12 A That's correct. It was on the level of
 13 ventilation to achieve an acceptable air quality
 14 level.
 15 Q And was there like a name of the group or the
 16 working group or the subcommittee that you were on?
 17 A Well, I will say I was on one subgroup that
 18 resulted in a paper that addressed sort of issues
 19 around defining acceptable air quality.
 20 The group was made up of some of the members
 21 who had health expertise. There were various other
 22 groups related to the tobacco smoking issue.
 23 Q So the -- the -- whatever the committee might
 24 have been called, you -- the end result was something
 25 that sought in the -- in the ASHRAE consensus approach

<p style="text-align: center;">Page 26</p> <p>1 to define what acceptable air quality standards were; 2 is that right?</p> <p>3 A Well, one issue that we took on was whether 4 such a definition was achievable.</p> <p>5 Q Did you conclude that it was?</p> <p>6 A We concluded that it was complex. That's 7 essentially what our paper says.</p> <p>8 Q And correct me if I'm wrong. But the focus 9 would have been on commercial buildings; is that 10 correct?</p> <p>11 A Correct. Commercial public buildings, yes.</p> <p>12 Q Okay. And did you -- did -- did your 13 contribution result -- strike that.</p> <p>14 Did ASHRAE ultimately promulgate any 15 definitions of acceptable indoor air quality for 16 commercial buildings?</p> <p>17 A Well, I will say that one follow-up was that 18 I chaired a committee for ASHRAE on secondhand smoke 19 that was a position document that said if there were 20 smoking in buildings, that acceptable air quality 21 could not be achieved.</p> <p>22 Q Okay. Did that subcommittee that you chaired 23 look at airborne pathogens?</p> <p>24 A No, it did not.</p> <p>25 Q Is there anything about the activities that</p>	<p style="text-align: center;">Page 27</p> <p>1 you did in connection with ASHRAE that you believe 2 gives you expertise in engineering issues related to 3 control of airborne pathogens?</p> <p>4 A I think by sitting with a group of 5 ventilation engineers for several years I gained a 6 general background in the operation of air-handling 7 systems within buildings.</p> <p>8 Q Do you feel that you have -- that carries 9 over into giving you insight into air-handling systems 10 in ultraclean operating theaters in hospitals?</p> <p>11 A Again, I don't think -- to -- to your point 12 not specifically. But as I said, a general 13 background.</p> <p>14 Q Let's talk about your -- your activities as 15 an epidemiologist.</p> <p>16 Broadly speaking, how do you define what 17 it -- what it is that you do as an epidemiologist?</p> <p>18 A I'm sorry. That's such a broadly speaking 19 question, I'm not sure what you're trying to ask me.</p> <p>20 Q Okay. Well, you don't, for example, design 21 medical devices; right?</p> <p>22 A Medical --</p> <p>23 Q Medical devices.</p> <p>24 A As an epidemiologist, no.</p> <p>25 Q You don't -- well, strike that.</p>
<p style="text-align: center;">Page 28</p> <p>1 Would you characterize your activities in the 2 field of epidemiology to be primarily focused on 3 causal relationships between the environmental 4 exposures and adverse health outcomes in pop- -- in 5 large populations?</p> <p>6 A I'm not sure I would describe what I do in 7 such a limited fashion. There are many other aspects 8 of the work I do.</p> <p>9 Q Have you ever had been asked to consult with 10 a hospital in trying to identify or control an 11 infectious outbreak?</p> <p>12 A No, I have not.</p> <p>13 Q Have you ever studied or written anything 14 about hospital infectious outbreaks?</p> <p>15 A No, I have not.</p> <p>16 MR. GORDON: Let me -- do you have 17 exhibit stickers?</p> <p>18 To speed things up, I'll just write the 19 numbers on them.</p> <p>20 Dr. Samet, let me show you what's been 21 marked as Samet Exhibit 1.</p> <p>22 (The aforementioned document was 23 marked Exhibit 1 for identification 24 by the reporter.)</p> <p>25 ///</p>	<p style="text-align: center;">Page 29</p> <p>1 BY MR. GORDON:</p> <p>2 Q And I will -- I want to first establish what 3 this is. I will represent to you that I did not 4 include your CV, but I tried to include the text of 5 your report; the -- your Exhibit C, the materials 6 considered; and Exhibit D, the state of condensation. 7 So I'm not representing this is the complete report 8 that you submitted, all the -- all the materials that 9 you submitted.</p> <p>10 But does this appear -- does Exhibit 1 -- 11 First of all, does that contain your entire 12 expert opinion or your opinions?</p> <p>13 A As submitted, yes.</p> <p>14 Q Okay. And so -- and that would be the first 15 twenty-four page of Exhibit 1; is that right?</p> <p>16 A Correct.</p> <p>17 Q And Exhibit C, which I believe is fourteen 18 pages, and it's entitled "Materials Considered"; is 19 that right?</p> <p>20 A That's correct.</p> <p>21 Q So I want to spend a little time on Exhibit C 22 for -- just for right now. Exhibit C is a listing of 23 all of the materials that you considered for -- 24 specifically for purposes of rendering your opinions 25 that are set forth? There's twenty-four pages.</p>

Page 30

1 A Yeah. Up to -- up to the time of March 30.
 2 Q Up to the time of March 30. You anticipated
 3 my next question.

4 Subsequent to March 30, have you reviewed any
 5 other materials that have in any way impacted your
 6 opinions in this matter?

7 A I've seen one additional peer reviewed
 8 publication by Augustine describing three --
 9 interrupted time series studies of fecal infections in
 10 three institutions with a switch from forced-air
 11 warming to conductive warming.

12 Q Had you ever seen that publication before or
 13 the journal in which it was -- well, strike that.

14 You said it was a peer reviewed publication.

15 How did you determine that?

16 A My understanding was that it was a peer
 17 reviewed journal.

18 Q Where did that understanding come from?

19 A I guess acceptance that it was in the journal
 20 that I thought was peer reviewed.

21 Q Did you do anything to investigate whether it
 22 was a peer reviewed journal?

23 A Specifically, no.

24 Q Did you do anything to investigate whether it
 25 was --

Page 31

1 Well, did you do anything to determine
 2 what -- whether the journal in which it was published
 3 was one that was widely read or -- or well respected
 4 in the -- in any particular medical fields?

5 A As I -- as I recall, the paper did have both
 6 a public -- sorry -- a submission and an acceptance
 7 date, which would imply to me that it was, in fact,
 8 peer reviewed.

9 I'm not specifically familiar with that
 10 journal versus other journals in the -- in that
 11 general area.

12 Q Have you -- you published hundreds of papers,
 13 haven't you?

14 A I've published hundreds of papers.

15 Q Have you ever had to pay to publish them?

16 A I'm sorry?

17 Q Have you ever had to pay to publish any of
 18 your publications?

19 A I would have to think because in today's
 20 online journal world, you sometimes pay. And whether
 21 some of my papers have to be in Class One [phonetic]
 22 or some of the journals where you pay. I'd have to
 23 look. That's something that's happening in today's
 24 publication world.

25 Q As you sit here today, can you remember

Page 32

1 having yourself to pay an online publisher to publish
 2 a paper you had authored co-authored?

3 A I would have to look because I think some of
 4 our recent online papers had been in such journals
 5 regarding global health, but I -- I can't pull up the
 6 details of that today.

7 Q This Augustine publication that you -- that
 8 you read, how did you come to learn about its
 9 existence?

10 A I actually learned about it from, uh,
 11 Jan Conlin.

12 Q Okay. And how long ago did you read it?

13 A Oh, initially, within the last ten days
 14 probably.

15 Q Did you -- one of the things that you
 16 indicated that you reviewed prior to rendering your
 17 opinions in this matter was the -- hold on. I
 18 misspoke. I apologize. I withdraw that.

19 Q Have you ever read the deposition of
 20 Scott Augustine?

21 A Well, I -- I will say that I have seen a
 22 number of depositions. Would -- in all honestly, I
 23 have difficult saying this is the reliance list here
 24 in terms of what I looked at.

25 Q I -- I'm sorry. Could you explain that. So

Page 33

1 Exhibit C is not a comprehensive --

2 A No. Exhibit C is what I looked at. I kind
 3 of --

4 Q Okay.

5 A Yeah.

6 Q And I assume you tried to be as comprehensive
 7 as possible.

8 A Yes. And reviewed the materials that I had
 9 in preparing this list.

10 Q I don't see the deposition of Scott Augustine
 11 included in the reliance materials.

12 Is that -- is that an oversight, or is
 13 that -- is that -- is it accurate that you did not
 14 read Dr. Augustine's deposition?

15 A Well, the -- the only thing I'm saying is
 16 that in preparing this list, we went through
 17 everything that was on hand in my office and had been
 18 sent to me. So unless we missed it, it's on here.

19 Q As you sit here today, do you have any
 20 independent recollection of having reviewed either the
 21 full Augustine transcript or any portions of his
 22 actual testimony?

23 A I -- I mean, again, I can't swear now having
 24 read through or at least skimmed through it. So many
 25 of these depositions. That one specifically.

1 Q Did you -- do you know if you had occasion to
 2 look at any of the exhibits that were marked at the
 3 Augustine deposition?

4 A I don't know.

5 Q Well, let me be more specific.

6 Do you recall when you saw this Augustine
 7 paper that you brought up that you said you saw maybe
 8 ten days ago, when you looked at it, did -- did you
 9 look -- did anything trigger a thought in your mind
 10 that "Gee, this looks like something I've already" --
 11 "at least part of something that I've already seen
 12 before"?

13 A Not specifically, no.

14 Q That appeared to be like brand-new material?

15 A (Nodding head.) Yes.

16 Q So as you sit here today, do you have any
 17 information about the background of how that Augustine
 18 study came to be prepared, the underlying data, any --
 19 any -- any information about it other than what was
 20 represented by Dr. Augustine in the publication
 21 itself?

22 A To my -- to my memory, my -- my
 23 understanding, that paper is based on reading it.

24 Q Has that paper had any impact on your
 25 opinions?

1 A I regard the paper as another piece of
 2 observational evidence that provides an estimate of
 3 risk of deep joint infection associated with the Bair
 4 Hugger device versus the comparison.

5 Q You -- ultimately, your opinion in -- the --
 6 the sort of the bottom line general opinion was that
 7 you concluded that the -- based on your
 8 epidemiological expertise, that the Bair Hugger -- use
 9 of the Bair Hugger in orthopedic surgery is a
 10 substantial contributing cause to the development of
 11 periprosthetic joint infection; is that right?

12 A That's the last sentence of my report,
 13 page 17.

14 Q I want to ask about this phrase "substantial
 15 contributing cause."

16 Is that a concept that's used in the field of
 17 epidemiology?

18 A Well, I think there are a number of different
 19 approaches taken to describe causation, strength of
 20 causation, contribution to cause. There's -- so I --
 21 it's -- it's a word that I have seen used or a phrase
 22 that I've seen.

23 Q It's not a phrase that you use, though;
 24 right?

25 A I think it would depend on the context.

1 If -- this refers to the magnitude of excess risk. So
 2 it's a description based on the odds ratio of the
 3 strength of association.

4 Q You've written or co-authored hundreds of --
 5 of papers and studies that looked at odds ratios,
 6 attributable risk, and things like that, and drawn
 7 causal conclusions; right?

8 A In -- in -- in various activities and not
 9 specifically in the context of my papers. I've worked
 10 on reports and other expert documents that had causal
 11 conditions.

12 Q Would it surprise you that not one of your
 13 publications has ever used the phrase "substantial
 14 contributing cause"?

15 A I -- I'm not sure what the basis for your
 16 statement is, but...

17 Q Would you -- would it surprise you that if
 18 you were to search everything that you've written,
 19 that the phrase "substantial contributing cause," that
 20 exact phrase, never appears in anything that you've
 21 authored or co-authored?

22 A I really don't -- don't -- just don't have an
 23 opinion.

24 Q Well, wouldn't you agree that -- that the
 25 notion of something being a substantial contributing

1 cause is not something that -- that you, at least in
 2 your professional activities as an epidemiologist,
 3 have looked at or -- or used as a reference point?

4 MS. CONLIN: Objection as to form --

5 THE WITNESS: Well --

6 MS. CONLIN: -- it mischaracterizes his
 7 testimony.

8 THE WITNESS: Well, again, I think in
 9 terms of the question of causation, there are
 10 two -- two issues.

11 One is, Does an agent cause whatever the
 12 outcome is that's being considered?

13 And the second is, What's the magnitude
 14 of its contribution to causation?

15 So certainly I've written about both
 16 aspects of causation; the question of Is an agent
 17 causal? And then second, What is its
 18 contribution?

19 BY MR. GORDON:

20 Q Well, what constitutes a substantial
 21 contributing cause as opposed to a contributing cause
 22 that isn't substantial?

23 A Well, you know, again, I don't have strict
 24 numerical criteria.

25 But here I think the basis for the

1 calculation is the simple attributable risk of the
 2 exposed which precedes the facts of the substantial
 3 contributing cause. That -- you know, that estimate
 4 is 74 percent as -- as stated in the sentence on
 5 page 17.

6 Q Would an attributable risk of 10 percent be a
 7 substantial contributing cause in your opinion?

8 MS. CONLIN: Objection; it calls for
 9 speculation.

10 THE WITNESS: I mean, I -- I -- again,
 11 10 percent is substantially lower than 74 percent.
 12 BY MR. GORDON:

13 Q As an epidemiologist, is there some either
 14 absolute number or -- or -- or general range of
 15 attributable risk that you would characterize as
 16 either substantial or not substantial?

17 A I don't -- I don't have bottom line cutoffs,
 18 if that's your question.

19 Q Well, I'm trying to -- my question is, How
 20 did you determine that -- that the attributable risk
 21 that you found was a substantial contributing cause as
 22 opposed to simply a contributing cause?

23 A Well, that was based on this estimate of
 24 74 percent of the attributable risk of the exposed.

25 Q And the attributable risk is derived from the

1 relative risk; right?

2 A It's based on the relative risk of the
 3 exposed, correct.

4 Q And that's just simply a mathematical --
 5 arithmetic computation; right?

6 A As shown here, it was a straightforward
 7 calculation.

8 Q But deriving a number for attributable risk
 9 when you have a relative risk, that's just a standard
 10 arithmetic calculation, RR minus -- divided by --

11 A Correct. That's provided in the sentence
 12 before.

13 Q So coming up with an attributable risk,
 14 that's not -- that doesn't involve any -- the
 15 application of any expertise once you provided
 16 relative risk; right? It doesn't involve any
 17 judgment, I should say?

18 A Well, it's a standard calculation.

19 Q Okay. So I -- once somebody derives a
 20 relative risk and the attributable risk is calculated
 21 either by you or somebody else, determining whether
 22 the attributable risk is substantial or not, that's --
 23 that's just a judgment call for you? Is that --

24 A Well, I --

25 Q -- what you're saying?

1 A I mean, again, here the figure is 74 --
 2 74 percent, which is, you know, the majority. So --
 3 of the risk of the exposed. So in that case, you
 4 know, the word "substantial" seemed applicable.

5 Q You have -- and that's -- we're going to be
 6 talking quite a bit today about the McGovern paper,
 7 and so let's define that.

8 You -- one of the items upon which your
 9 report is based was the -- a paper published in 2011
 10 that is listed as Item Number 49 on your materials
 11 considered list; is that correct? McGovern, Albrecht,
 12 Belani, et al.

13 A That's right.

14 Q "Forced-air warming and ultra-clean
 15 ventilation do not mix: An investigation of theatre
 16 ventilation, patient warming and joint replacement
 17 infection in orthopaedics."

18 A Correct.

19 Q So when I -- when I refer to the McGovern
 20 study -- we could -- at some point we could mark it.
 21 Probably will.

22 But is -- is that this reference, Number 49,
 23 that I'm referring to, sir?

24 A That's fine.

25 Q Okay. And that -- the -- the relative risk

1 of 3.8 from which you derive attributable risk of
 2 74 percent, that came out of the McGovern paper;
 3 right?

4 A That is correct.

5 Q And you have looked at all of the underlying
 6 raw data that had -- hadn't been made available to
 7 anyone for that McGovern paper; right?

8 A I did not look at the actual raw data.

9 Q You never looked at it?

10 A I have seen the representations of what is
 11 said to be the raw data in discussions of it. But I
 12 did not directly examine, count, or compile the raw
 13 data.

14 Q I don't understand what you mean.

15 What -- what -- have you seen the -- what
 16 you're characterizing as representations of what --
 17 How -- how did you phrase that?

18 A I've seen printouts of data sets that are
 19 attributed to being perhaps the original data. I
 20 believe I saw that in Albrecht's report, perhaps.

21 Q Well, let's go back to your materials
 22 considered list. I want to understand something about
 23 that.

24 For the list of -- of depositions, the first
 25 page of Exhibit C, you list nineteen depositions;

1 right?
 2 A I'm not --
 3 Q They're numbered, I think.
 4 A Sorry. Which page is this?
 5 Q Page 1 of Exhibit --
 6 MS. CONLIN: C.
 7 BY MR. GORDON:
 8 Q -- C.
 9 A Okay.
 10 Q So there are -- you list nineteen deposition
 transcripts and exhibits.
 11 A That's correct.
 12 Q Now, for some of the transcripts, you -- you
 identified the -- the deponent, the date, and you say
 13 final deposition transcript and Exhibits 1 through
 14 blank, whatever they put on those. Like Gary Hansen
 15 or Al Van Buren [phonetic], Numbers 5 and 6.
 16 Is that right?
 17 A That's correct.
 18 Q But for several of these, you don't say
 19 anything about exhibits. You just say, for example,
 20 Example Number 1, Kumar Belani, September 7, 2016,
 21 final deposition transcript.
 22 A Yes.
 23 Q I don't want to assume anything.

1 Where you don't list exhibits, does that mean
 2 you didn't review the exhibits if there were any or
 3 that you just didn't list that?
 4 A This is a list of material -- I had materials
 5 that were provided by Ciresi Conlin, and -- and this
 6 is a straightforward compilation of what was on hand
 7 done by my research assistant.
 8 Q So your assistant -- this was a review of
 9 material by a research assistant?
 10 A Sorry.
 11 Q In reviewing the material that -- on which
 12 you relied for your report, you were assisted by a
 13 research assistant?
 14 A No. I had a research assistant to organize
 15 these materials and try to keep everything organized,
 16 if you will.
 17 Q Okay. Well, can -- would it be correct to
 18 conclude that if there are no exhibits listed for a
 19 particular deponent, such as Kumar Belani, that would
 20 mean that you didn't review any exhibits, you just
 21 reviewed the transcript?
 22 A That would be correct.
 23 Q Okay.
 24 A These are the materials we had.
 25 Q And I'm curious because you made reference to

1 Albrecht, the exhibit that you described as the
 2 printout of a data set. You're listing the two
 3 deposition transcripts for Mark Albrecht. It
 4 showed -- it doesn't list any exhibits.
 5 A Yeah. No. These were provided as -- to me
 6 as background in reviewing the reports from
 7 Drs. Holford and Borak.
 8 Q So prior to rendering your opinion, you
 9 hadn't seen --
 10 A That's correct.
 11 Q -- the data set?
 12 A That's correct. It's more recently that saw
 13 a thick compilation of the printout.
 14 Q Okay.
 15 A What was said to be a compilation.
 16 Q Okay. Just so we're clear. So when you
 17 read -- or -- excuse me.
 18 When you rendered your opinion on March 30th,
 19 you had not looked at anything that purported to be
 20 underlying raw data for the McGovern paper; is that
 21 correct?
 22 A I had not.
 23 Q So -- so if a representation was made to the
 24 court that you looked at all the evidence, all the
 25 underlying raw data, and concluded that McGovern is an

1 absolutely valid study, that would be not be a correct
 2 representation --
 3 MS. CONLIN: Objection --
 4 BY MR. GORDON:
 5 Q -- correct?
 6 MS. CONLIN: -- as to --
 7 THE WITNESS: Again, as I -- as I said,
 8 up to the time of March 30, I had not seen raw
 9 data from the McGovern study.
 10 BY MR. GORDON:
 11 Q And you wouldn't have analyzed it, obviously,
 12 then to make a determination as of March 30 that the
 13 McGovern study was an absolutely valid study; right?
 14 A Well, I -- the McGovern study was published
 15 in the peer reviewed literature. Again, reanalysis of
 16 the raw data is not necessarily a requisite standard
 17 for validity.
 18 Q And you didn't do any reanalysis; correct?
 19 A That's correct.
 20 Q Did you make any independent determination
 21 that the McGovern paper was a valid study?
 22 A I guess I'm not sure what you mean by a
 23 "valid study."
 24 Q Does the concept of a valid study versus an
 25 invalid study have any meaning in the field of

1 epidemiology?

2 A Again, there are many, many aspects of the
3 manuscript that one would look at to decide about what
4 it shows.

5 I just simply don't classify things as a
6 valid study or an invalid study based on -- in the way
7 I think you're using these terms.

8 Q Well, I'm just --

9 Would it be fair to say that you did not
10 independently come to any conclusion regarding the
11 validity of the McGovern study?

12 A Okay. Again, I'm a little puzzled by the
13 word "validity" as you -- as you used it. I have not
14 carefully read what was in the published manuscript
15 and -- and interpreted it.

16 Q Well, I'm just -- I'm just trying to
17 understand. Somebody represented to the court in this
18 case that you, Dr. Samet, had reviewed all the
19 underlying raw data and concluded that McGovern --
20 that McGovern was an absolutely valid study.

21 We've already established that you -- that
22 would be wrong because you didn't look at the
23 underlying data, and that would also be wrong because
24 the concept of being an absolutely valid study doesn't
25 have any -- any significance, it doesn't mean

1 anything; right?

2 A I -- I really don't understand what you're
3 saying. I'm not sure I know what you mean by
4 "absolutely valid."

5 Q It sort of doesn't matter what I'm --

6 Is -- is there any meaning of that phrase
7 that you would use that would allow you to say "Well,
8 yes, I did. I did draw an independent conclusion that
9 it was an absolutely valid study"?

10 A Again, if I -- to use my words, I would look
11 for the study and the conclusion and the methodology
12 as described and the potential for there to be a
13 source and a debate about bias.

14 Q And as of March 30 when you rendered your
15 opinions in this case, you had concluded that there
16 were no sources of bias; is that right?

17 A There were no major sources.

18 Q No major sources of bias.

19 Did you determine there were any minor
20 sources?

21 A Well, I -- I think -- in epidemiology and
22 doing observational studies, there may be sources of
23 bias that are, you know, there but not well-described.
24 But here at least I did not see any major sources of
25 bias.

1 Q And how would you characterize --
2 What would you characterize as a major source
3 of bias? I want to use the right phraseology.

4 A Well, I mean, the -- the issues that affect
5 any observational study are threefold. One is
6 confounding, one is problems in measurement, and the
7 third is selection bias.

8 Q And by "measurement," do you mean
9 quantification or tabulation or both?

10 A Error in measurement.

11 Q Would tabulation error be considered a
12 measurement error?

13 A It could be if anything was tabulated.

14 Q And what -- what do you mean by selection
15 bias?

16 A Selection bias is a form of bias that arises
17 from differential participation or dropout from the
18 study in a way that distorts the exposure-outcome
19 relationship.

20 Q And going back to the first potential source
21 of major bias, confounders.

22 You concluded that there were no confounders
23 that would rise to the level of major bias in the
24 McGovern study; right?

25 A That's correct. I concluded that there was

1 no source of confounders that would have led to the
2 estimated level of bias.

3 Q And the only sources of confounding that you
4 mentioned in your report were the prophylactic
5 antibiotic regimen and the thromboprophylaxis regimen;
6 correct?

7 A Correct.

8 Q Did you look at any other potential
9 confounders in the McGovern study besides antibiotics
10 and thromboprophylaxis?

11 A Well, from the information provided -- let --
12 let me step back.

13 A confounder here would have to be something
14 that differed in the two time periods of observation,
15 the Bair Hugger period and the conductive warming
16 period. And that in itself was a risk factor for deep
17 joint infection.

18 So that -- that is a requirement. And from
19 the information available in the publication, there
20 was not an indication of other confounders.

21 Q Based on what was actually in the paper?

22 A Based on what was actually in the paper.

23 And the other comment I would make is, aside
24 from the transition period -- the two-month transition
25 period, any potential temporal confounder would have

Page 50

1 to change rather quickly to introduce bias.
 2 Q And in order for you to have determined that
 3 something is a confounder -- correct me if I'm wrong.
 4 But it's your -- your expert opinion that a particular
 5 risk factor has to independently achieve statistical
 6 significance. Otherwise, it -- it is disregarded, it
 7 doesn't have an impact, it has no results.

8 A It does not necessarily have to achieve
 9 statistical significance to be a confounder.

10 Q So something that isn't -- it potentially
 11 impacts an outcome, but doesn't do so in a
 12 statistically significant way could nevertheless
 13 confound a study?

14 A If it met the criteria of being associated
 15 with the factor and was also an independent risk
 16 factor on its own.

17 Q If bias being -- when you say being
 18 associated with it and an independent risk factor on
 19 its own, would the association have to be
 20 statistically significant in order for it to be
 21 considered a --

22 A I'm sorry. Which association?

23 Q Just hypothetically. If you're looking at
 24 the question of does X cause Y, and you compared two
 25 groups, one that was exposed to X and one that was not

Page 51

1 exposed to X, and the outcome Y.
 2 That's pretty standard epidemiological study;
 3 right?

4 A Well, it might be a standard data set.
 5 That's correct.

6 Q Okay. And -- and if --
 7 THE WITNESS: Jan.
 8 (The witness handing glass to
 9 Ms. Conlin.)

10 BY MR. GORDON:

11 Q -- some of the people in one group that you
 12 were comparing to also had an exposure to Z, factor Z,
 13 and the people in the group to which you were
 14 preparing that group had no exposure to Z, it's
 15 possible that Z could be an independent risk factor
 16 for outcome Y; right?

17 A Well, that would depend on what is known
 18 about Z, and is it, in fact, a predictor of a risk
 19 factor for the outcome.

20 Q Okay. Let's -- and that's what I'm
 21 talking -- I want to talk about Z. For it to be a
 22 risk factor that you would consider a confounder that
 23 could give rise to concerns of major bias, does Z have
 24 to be --

25 Well, first of all, it would have to be an

Page 52

1 independent risk factor, right --

2 A That's correct.

3 Q -- because Z has an association with Y
 4 independent of X; right?

5 A I'm getting a little confused by X, Y, and Z,
 6 but yes.

7 Q Okay. Does Z have to be associated with the
 8 outcome Y independently but in a statistically
 9 significant way in order for it to be considered a
 10 potential confounder that would give rise to concerns
 11 of substantial bias?

12 A I'm sorry. I think -- if you don't mind,
 13 I'll try and say it better.

14 Q Please put it in your words.

15 A That -- that our hypothetical confounder Z --
 16 if I understand, your question is, Is it requisite for
 17 confounding that it be statistically significantly
 18 associated with X? Is that --

19 Q I think the outcome was Y, but that's fine.

20 A Y.

21 Q Whatever --

22 A Y. All right. Probably better to start
 23 over.

24 Q You know what, let's -- let's stop the
 25 algebra. I apologize that, for getting us off on

Page 53

1 that.
 2 One of the issues you looked at was whether
 3 use of rivaroxaban as a proper prophylaxis could have
 4 been a -- a confounder in your medical opinion;
 5 correct?

6 A Yes, that's right.

7 Q Rivarox -- rivaroxaban was used for part of
 8 the Bair Hugger only period but not at all in the
 9 HotDog period; right?

10 A Correct.

11 Q So if rivaroxaban was an independent risk --
 12 risk factor for the outcome of -- of joint infections,
 13 it could be a confounder to any causal determination
 14 of -- of the impact of Bair Hugger versus HotDog;
 15 right?

16 A I -- in responding, I want to emphasize that
 17 you said if it is a risk factor for deep joint
 18 infection, which I'm not aware that that is actually
 19 established.

20 That is a high -- the requisite requirement
 21 for -- for a confounder is it would be an independent
 22 risk factor, which is a matter of judgment based on,
 23 you know, what is known in general about the potential
 24 confounder.

25 Q And -- and -- well, specifically in the case

<p style="text-align: center;">Page 54</p> <p>1 of rivaroxaban, you determined that it was not a risk 2 factor, right -- I mean, the benefit risk factor?</p> <p>3 A Excuse me.</p> <p>4 It seems -- it seems unlikely. I mean, 5 as I thought about this, I struggled with why a -- 6 an agent that's a thromboprophylactic agent would 7 increase the experience of infection, particularly 8 when administered postsurgery.</p> <p>9 So this was a judgment that's, you know, 10 perhaps not fully spelled out here, but it was 11 based on what was within the data set and other 12 considerations.</p> <p>13 Q Okay. And -- and, obviously, I can't know 14 what the considerations were that -- that led you to 15 the conclusion that weren't in your report. So, you 16 know, now is my time to get -- to ask you these 17 questions. I --</p> <p>18 Please tell me everything you considered in 19 coming to the judgment that in the McGovern study the 20 use of rivaroxaban for seven months in the Bair Hugger 21 only period was not an independent risk factor for 22 developing joint infection.</p> <p>23 A Well, you know, again, I -- as I -- as I 24 said, I questioned how an agent used for 25 thromboprophylaxis would plausibly increase risk for -</p>	<p>1 for infection.</p> <p>2 I looked at -- I think it was a Jensen 3 publication that provides some -- some relevant 4 information.</p> <p>5 And to my understanding, this is an agent 6 that is also administered after surgery is completed. 7 Of course there's a risk for -- for bleeding, which, 8 to me at least, again leads to questions about the -- 9 the plausibility of it being a, quote, "independent 10 risk factor."</p> <p>11 I recognize that different -- as you said, 12 different agents for thromboprophylaxis were used at 13 different points in this time series.</p> <p>14 Q You mentioned Jensen.</p> <p>15 Did you conduct any independent research into 16 the medical literature to see if anyone else besides 17 the Jensen, et al., authors had looked at whether 18 rivaroxaban as a thromboprophylactic agent in joint 19 replacements could -- could impact infections?</p> <p>20 A Well, you know, again, there are, as I 21 recall, some other relevant studies. I think the 22 record study -- there was a group of investigations.</p> <p>23 I mean, you know, this -- in a sense, it's 24 hard to study. Deep joint infection is not 25 particularly common, making it difficult to do</p>
<p style="text-align: center;">Page 56</p> <p>1 well-powered studies.</p> <p>2 Q Was the McGovern study well-powered in your 3 opinion?</p> <p>4 A That's a question that I would not answer 5 that way. I mean, it's a -- a somewhat limited period 6 of observation for an event that is not uncommon -- 7 I'm sorry -- that is not common. The results, as 8 presented in the original report, were statistically 9 significant.</p> <p>10 Q I may have misread your -- your opinions, so 11 I want to clarify my understanding.</p> <p>12 Was one of the reasons you came to the 13 conclusion that rivaroxaban was not an independent 14 risk factor was the fact that the Jensen paper 15 concluded that the increase that they reported in 16 joint infections during the rivaroxaban period was -- 17 did not reach a statistical significance?</p> <p>18 A I -- you know again that's certainly a part 19 of the story that -- to look at. And the outcome they 20 had admittedly for deep joint infection might have 21 been subject to some misclassification.</p> <p>22 But as I recall, it was a -- a grouping. But 23 it certainly did not provide strong evidence that 24 rivaroxaban/Xarelto was a strong -- an independent 25 risk factor.</p>	<p style="text-align: center;">Page 57</p> <p>1 Q Did it provide -- do you recall, did it 2 provide evidence that rivaroxaban wasn't at all a risk 3 factor, whether it was strong or weak?</p> <p>4 A Studies don't usually provide evidence that 5 something is, quote, "not at all a risk factor." To 6 be -- I think I mentioned in the context safety in 7 here, that would require a very narrow -- a -- a 8 striking degree of precision around an estimate to say 9 something is, quote, "absolutely safe."</p> <p>10 Q Putting aside the Jensen study for a moment, 11 did you do any research into the medical literature to 12 see if there were any other studies on the impact of 13 rivaroxaban on joint infections in joint replacement 14 surgeries?</p> <p>15 A I did not do a systematic search.</p> <p>16 Q Do you do a nonsystematic search?</p> <p>17 A I -- you know, again, I saw several articles. 18 But I did not do a systematic review, if that's the 19 question.</p> <p>20 Q And all the several articles that you saw, 21 would they all be listed on Exhibit C?</p> <p>22 A At least two of the main ones, the Jensen and 23 the Jameson, yes.</p> <p>24 Q And as you look over this list of materials, 25 is there anything else besides Jensen and Jameson that</p>

Page 58

1 you reviewed that in any way addressed the issue of
 2 whether rivaroxaban could be an independent risk
 3 factor for joint infection?

4 A As I -- as I said, beyond those two, I did
 5 not do a systematic search to this point.

6 Q Okay. How is it that you chose to review and
 7 rely on Jensen and Jameson?

8 A Well, I -- in the -- in -- on page 9, I
 9 provided a list of the search strategies of where
 10 articles came from. And similar to this net that
 11 arose, I can't say specifically which approach, which
 12 search resulted in those two articles. But the
 13 strategy is laid out there.

14 Q Okay. And let's -- I want to -- I want to be
 15 clear. Is it your testimony that every single one of
 16 the papers that cropped up or -- strike that.

17 Is it your testimony that all ninety-six of
 18 the publications that you list in Exhibit C were
 19 independently gathered by you as a result of these
 20 search parameters that you list on page 9 of your
 21 report?

22 A Well, page 9 describes the whole strategy,
 23 which included the literature that did come from
 24 Ciresi and Conlin, my own literature searches, and
 25 expert reports that I read.

Page 60

1 going for a while. If you want to take a break,
 2 we can --

3 THE WITNESS: Well, that would
 4 probably --

5 MS. CONLIN: That's fine.

6 THE WITNESS: -- you know, what we're
 7 doing.

8 MR. GORDON: This isn't a marathon.

9 MS. CONLIN: I don't know what --

10 THE WITNESS: That's good to know.

11 What?

12 MS. CONLIN: Let's -- why don't we take a
 13 five-minute break. I mean --

14 MR. GORDON: Yeah.

15 MS. CONLIN: -- when you get to a
 16 convenient spot, that be fine with me.

17 THE WITNESS: Actually, five minutes
 18 would be --

19 MS. CONLIN: Okay. That's fine.

20 THE VIDEOGRAPHER: The time is 12:12 p.m.
 21 We are off the record.

22 (A brief recess was taken.)

23 THE VIDEOGRAPHER: We are back on the
 24 record. The time is 12:27 p.m.

25 MR. GORDON: I just want to -- we've been

Page 59

1 Q And thank you for clarifying that.
 2 Some of the literature upon which you relied
 3 was provided to you by Ciresi Conlin; right?

4 A And, you know, again, I can't speak to this
 5 directly. I'm sure probably the same papers were
 6 identified in the literature searches.

7 Q Would it surprise you if you were to run a
 8 PubMed search using all of the search terms on
 9 Exhibit 9, that would you not find either the Jensen
 10 or the Jameson paper?

11 A As I said, I don't know which were found by
 12 which means.

13 Q So as -- right as you sit here today, you
 14 have no independent basis for -- for saying that
 15 either the Jensen or the Jameson paper did or did not
 16 come out of your own search efforts as set forth in
 17 Exhibit -- page 9 versus something that was provided
 18 to you by Ciresi Conlin?

19 A As a general comment, I did not tag things
 20 one way or the other.

21 Q And unless it was --

22 A Just one second. One second. I lost my
 23 mike.

24 Q Oops. I'm sorry.

25 MR. GORDON: And by the way, we've been

Page 61

1 talking about it a lot, so I just wanted to --
 2 we'll mark it separately so there's no question
 3 what we're talking about.

4 I'll show you what's been marked Samet
 5 Exhibit 2. It was also previously marked as
 6 Albrecht Exhibit 8.

7 (The aforementioned document was
 8 marked Exhibit 2 for identification
 9 by the reporter.)

10 BY MR. GORDON:

11 Q Is -- Samet Exhibit 2, is that the McGovern
 12 paper that we've been talking about?

13 A Yes, it is.

14 Q There are actually two components to this
 15 study, correct, of mechanistic components looking at
 16 bubbles and airflow and then the observation of the
 17 components?

18 A That's correct.

19 Q And you -- and your conclusions relating to
 20 the odds ratio, the attributable risk, those things in
 21 your report, that's are all based on the observational
 22 component of the McGovern paper that we've now marked
 23 as Exhibit 2?

24 A The quantitative discussions based on the
 25 observational component, correct.

Page 62

1 Q And one of the reasons you conclude that the
 2 odds ratio that is reported, the relative risk that is
 3 reported is not influenced by any confounders is the
 4 fact that it is a strong association; is that correct?

5 A In part, yes.

6 Q Anywhere in part.

7 And tell me -- well, strike that.

8 Would you -- would you agree that -- that
 9 generally in the epidemiological literature,
 10 associations are usually categorized as weak,
 11 moderate, or strong?

12 A I -- people may do that. I personally don't.

13 Q You don't?

14 A No.

15 Q Okay. So is it binary for you? Something
 16 is -- an association is either strong or it's not
 17 strong?

18 A I think the numbers speak for themselves.

19 Q Well, what's a strong association?

20 A I -- I -- again, I rely not on adjective
 21 descriptors in -- in general but on the description of
 22 what the actual estimate is.

23 Q So would you rely on 3. -- a relative risk of
 24 3.8 as a -- as evidence of a strong association? That
 25 a relative risk of 3.8, in your opinion, constitutes

Page 64

1 eliminates the possibility of -- of confounders?
 2 Would you say that 3.7 was a moderately strong
 3 association that would give you reason to -- a comfort
 4 level that there -- that that's not a result of
 5 confounding?

6 A I -- it's not so simple a question. It
 7 really depends -- it depends on the relevant
 8 confounder set and how strong confounders might be
 9 as -- as risk factors for the outcome of it.

10 Q So it's not be the number in the abstract
 11 that allows to you decide whether it's a moderately
 12 strong association or not? There are some other
 13 factors that you consider in conjunction with the
 14 actual relative risk number?

15 A I'm sorry. You're speaking to the strength
 16 of the relative risk or confounding?

17 Q Well, I'm focusing on -- on page 16 where you
 18 say (reading):

19 "With respect to the Hill
 20 criteria" -- "Hill postulates, that
 21 with respect to strength of
 22 association, the available
 23 observational evidence indicates a
 24 moderately strong association."

25 And you discussed McGovern and say

Page 62

1 based on association; is that right?

2 A Actually, I'm not sure I applied the word
 3 "strong." I'd have to look through my report.
 4 (Witness reviewing document.)

5 THE WITNESS: I discussed strength of
 6 association on page 16. I did not -- I said
 7 moderately. It says "moderately strong."
 8 Page 16.

9 BY MR. GORDON:

10 Q Moderately strong association.

11 Okay. Tell me, in your stratification of --
 12 of a strength of association, what -- what are the
 13 different categories? Is there --

14 A Again --

15 Q Is it moderately strong? You know, strongly
 16 strong? Weakly strong? I -- I'm not --

17 A That's why. I just can't give you a
 18 Jonathan Samet classification where I have a set of
 19 standard descriptors I would use.

20 Q Okay. But to you, 3.8 is moderately strong?

21 A Correct.

22 Q And would -- would you consider a 3. -- if
 23 somebody said "Dr. Samet, I've got a" -- "got some
 24 observation study that concluded that there was a
 25 relative risk of 3.7," do you think that kind of

Page 64

Page 65

1 (reading):

2 "The relative risk is estimated
 3 at 3.8."

4 And, you know, I -- I'm -- I'm pretty
 5 sure I saw it somewhere else. You did link that.

6 Yeah, I -- I think what I was -- thank
 7 you for pointing me to that. What I was thinking
 8 of is on page 12 where you said that (reading):

9 "A more general argument
 10 against confounding can also be
 11 made. In setting aside whether the
 12 antibiotics and/or
 13 thromboprophylaxis were truly
 14 confounding, the magnitude of the
 15 association, 3.8 odds ratio
 16 reported by McGovern, et al.,
 17 deserves consideration."

18 You say that (reading):

19 "Such confounding is not only
 20 unlikely but is not supported by
 21 the evidence considered above and
 22 reviewed by Professor Nachtsheim
 23 and Drs. McGovern and Reed."

24 Right?

25 A Correct.

1 Q By the way, you didn't mention the
2 consideration given to that specific question by
3 Mr. Albrecht.
4 Had you read his deposition, either of the
5 transcript days, at the time you wrote this?
6 A I -- I -- you know, again, I'm just going to
7 have to plead fuzziness on what I read and when. I
8 just simply --
9 Q Fair enough.
10 A -- can't tell you.
11 Q Do you know who Mr. Albrecht was?
12 A I heard -- I understand that he's an analyst
13 and that he had -- that -- I don't know his full
14 professional history, but I've heard a little bit
15 about him.
16 Q Well, did you -- did --
17 Were you aware that he did the statistical
18 analysis in the McGovern paper?
19 A I'm aware of that, yes.
20 Q And were you aware that he worked for
21 Scott Augustine's company, Augustine Biomedical?
22 A I'm aware that he did. I don't know his full
23 history. I -- I understand that he did. And perhaps
24 now he's not. I don't know.
25 Q Okay. Well, do you know who --

1 Q You were never told that he was convicted of
2 Medicaid fraud by the company?
3 A I don't know his history.
4 Q And have you -- you haven't read his
5 deposition; right?
6 A It's not -- it's not -- it's not listed.
7 Q Okay. We'll talk about it then later.
8 The -- in your -- on page 12 when -- you're
9 talking about that -- your decision to set aside
10 whether the anti- -- the antibiotics and/or
11 thromboprophylaxis is truly confounding; right?
12 A That is correct.
13 Q Okay. You used -- again, I want to focus in
14 on that phrase "and/or."
15 You weren't just considering antibiotics
16 alone as a risk factor -- independent risk factor and
17 thromboprophylaxis alone as an independent risk
18 factor.
19 You also considered whether it was possible
20 that the combination of the antibiotic regimen and the
21 thromboprophylaxis regimen together could have been a
22 confounding factor?
23 A I think, if I can -- I'm not sure what you're
24 asking, if you're asking is -- was I considering
25 whether there was some form of, quote, "interaction

1 First of all, do you know who Scott Augustine
2 is in relationship to the Bair Hugger?
3 A My -- I think I do, yes.
4 Q What's your understanding?
5 A My understanding is he was the original
6 developer of the Bair Hugger device.
7 Q Okay. And what's your understanding of
8 what --
9 Is he still -- still involved with the
10 mark- -- manufacturing and marketing of the design?
11 Anything to do with -- with the Bair Hugger device?
12 A No.
13 Q Do you know what he does now?
14 A I -- I believe he has his own company.
15 Q What does it do?
16 A I think it makes another warming device.
17 Q Do you know what it's called?
18 A I think it's called the HotDog or something
19 equivalent.
20 Q That's -- and that's -- that -- that was the
21 comparatory device in the McGovern paper; right?
22 A Correct.
23 Q Do you know why Scott Augustine left the
24 company that he started that made Bair Hugger?
25 A No.

1 between the two."
2 Here my and/or referred to antibiotic use or
3 to thromboprophylaxis and not to particular
4 combinations of the possibilities of those two.
5 Q You understand that in the McGovern study
6 during the Bair Hugger only period, there were two
7 different antibiotic protocols --
8 A Yes.
9 Q -- used versus one in the HotDog period;
10 right?
11 A I understand that, yes.
12 Q And you understand in the Bair Hugger period,
13 there were two different thromboprophylaxis protocols
14 used; and in the HotDog period, there was only one --
15 A Correct.
16 Q -- thromboprophylaxis?
17 Prior to your writing your report, were you
18 aware that there was a period in the Bair Hugger only
19 time period that was reported by McGovern, et al.,
20 where the Bair Hugger patients, the Bair Hugger
21 cohort, had the same antibiotics and
22 thromboprophylaxis as was used for all of the HotDog
23 patients?
24 A I'm sorry. Can you say that again.
25 Q Prior to rendering your opinion and writing

1 your report, were you aware that there was a period of
 2 time during the HotDog or -- strike that.

3 Were you aware that there was a period of
 4 time during the Bair Hugger only time period where the
 5 identical antibiotic and thromboprophylaxis regimen
 6 was used as was used for the entire Bair -- HotDog
 7 only period?

8 A I think -- I think I was. And of course
 9 since then, I've seen the Holford report, which goes
 10 into this in great detail and lays out the diagram.

11 So I have a little trouble separating the pre
 12 March 30 with post. But I looked carefully at what
 13 was in the different intervals.

14 Q Oh, did -- I lost -- thanks. I'm sorry.
 15 A Oops. Give me a moment to repair, please. I was
 16 sitting on it. Okay. Okay.

17 Q Do you know Professor Holford?

18 A I know who he is. I think we probably met.
 19 I'm familiar with his work, yes.

20 Q You cited it on occasions?

21 A Yes.

22 Q Do you -- do you respect him as an authority
 23 in -- in the field of biostatistics?

24 A I think he's well-known and a well-regarded
 25 figure, yes.

1 What -- are there any other things that
 2 you -- you reviewed relating to the Bair Hugger
 3 that -- since your -- since you rendered your opinion?

4 A You mean that are in addition to?

5 Q In addition to the Augustine article, you
 6 mentioned the -- the printout of a data set and the
 7 Holford report.

8 A Oh, Dr. Borak's report.

9 Q Okay. Any -- any other of our -- of
 10 defendant's expert reports?

11 A I don't think so.

12 Q Did you read Professor Wenzel's report?

13 A Professor --

14 Q Richard Wenzel.

15 A I did see his report.

16 Q When you say -- I want to -- I mean, maybe
 17 it's semantics.

18 A When you say you saw it, does that -- you
 19 mean you -- you read it or --

20 A It was provided to me, and I read it, yes.

21 Q You read it cover to cover?

22 A I read it cover to cover but not -- not
 23 nearly so carefully as the Holford and Borak reports.

24 Q Okay. And which also makes me -- leads me to
 25 a question about the -- your reliance materials,

1 Q When did you read his report?

2 A I'm sorry. You're referring to his --

3 Q Well, I may have misunderstood. I thought
 4 you said you -- I'm not -- I -- let's clarify.

5 MR. GORDON: I'm going to mark this as
 6 Exhibit 3.

7 (The aforementioned document was
 8 marked Exhibit 3 for identification
 9 by the reporter.)

10 BY MR. GORDON:

11 Q I'll represent to you that this is the expert
 12 report in the exhibits that were submitted by
 13 Professor Holford on behalf of the defendants in this
 14 multidistrict litigation.

15 A Have you seen this before?

16 Q Yes, I have.

17 A And when did you first see this?

18 Q Perhaps a month and a half ago. Again
 19 just -- just guessing.

20 Q Okay. And so I want to be -- before when we
 21 talked about things you have seen since you rendered
 22 your opinion, you mentioned the Augustine publication.

23 Then -- I -- I thought you had mentioned
 24 this, but I want to clarify that. And I thought you
 25 also mentioned a printout of a data set.

1 A What -- are there any other things that
 2 you -- you reviewed relating to the Bair Hugger
 3 that -- since your -- since you rendered your opinion?

4 Q You mean that are in addition to?

5 A In addition to the Augustine article, you
 6 mentioned the -- the printout of a data set and the
 7 Holford report.

8 Q Oh, Dr. Borak's report.

9 Q Okay. Any -- any other of our -- of
 10 defendant's expert reports?

11 A I don't think so.

12 Q Did you read Professor Wenzel's report?

13 A Professor --

14 Q Richard Wenzel.

15 A I did see his report.

16 Q When you say -- I want to -- I mean, maybe
 17 it's semantics.

18 A When you say you saw it, does that -- you
 19 mean you -- you read it or --

20 A It was provided to me, and I read it, yes.

21 Q You read it cover to cover?

22 A I read it cover to cover but not -- not
 23 nearly so carefully as the Holford and Borak reports.

24 Q Okay. And which also makes me -- leads me to
 25 a question about the -- your reliance materials,

1 A Exhibit C, in your report.

2 Q When you list these -- these -- all of these
 3 items, are these things that you actually sat down and
 4 read from beginning to end or --

5 A No.

6 Q Okay.

7 A Actually, I scanned many of them. And some
 8 of them, I read beginning to end.

9 Q Can you tell me, starting with the deposition
 10 transcripts, did you read any of those deposition
 11 transcripts from beginning to end?

12 A I did. Now, as to which ones, it would be --
 13 it really would be a challenge because a lot of -- you
 14 know, a lot of materials are included here. And I,
 15 frankly, would have a hard time sort of saying I read
 16 that much of this one or that much of that one. It
 17 would be very difficult.

18 Q Did you read -- did you read either of
 19 the days of Mark Albrecht's testimony from beginning
 20 to end?

21 A I definitely read much of his testimony.
 22 Whether I read it beginning to end specifically, I
 23 just couldn't say sitting here today.

24 Q Would you have read much of it prior to your
 25 rendering your opinion on March 30?

1 A I probably did. I looked at these as they
2 came in. I can't comment on the specific time.

3 Q Have you reviewed any of the materials that
4 are listed on Exhibit C since March 30 prior to today?

5 A No.

6 Q So whatever -- whatever you reviewed about
7 Albrecht -- or --

8 Whatever part of Albrecht you've reviewed,
9 you reviewed it prior to rendering your opinion?

10 A Yes. And I may have looked -- again, you
11 know, I think I've gone back and looked at some of the
12 McGovern bits and -- bits and pieces. But primarily
13 most -- most of this was read before March 30.

14 Q Do you remember a discussion in the Albrecht
15 deposition that concerned the -- the issue that we
16 were discussing a few moments ago, the fact that there
17 was a time period within the Bair Hugger study when
18 antibiotics and thromboprophylaxis were the same as
19 used in the HotDog period?

20 A I can't say specifically.

21 Q So would you agree just as a general
22 proposition if you were interested in seeing if
23 antibiotics and thromboprophylaxis could have been a
24 confounder as between Bair Hugger and HotDog, the best
25 way to eliminate the possibility of the -- of them --

1 those two things being a confounder would be to
2 compare a time period within the Bair Hugger time
3 period where the same antibiotics and
4 thromboprophylaxis -- prophylaxis was used as was
5 used in the Bair Hugger era and the HotDog period?

6 A That -- that would be one approach. But it
7 would come at the price of reducing the size of the
8 data available.

9 Q Prior to your rendering your opinion, did
10 you -- did you try to do that?

11 A As I said already, I did not do any primary
12 data analysis.

13 Q Do you recall -- well, have you, as you sit
14 here today -- I mean, when you said that there would
15 be a price to pay, I'm assuming that you somehow have
16 learned that there was a time period and have some
17 sense as to how -- what that time period was
18 length-wise or -- or number of patients-wise.

19 Right?

20 A There were -- there were some months. And
21 I -- perhaps it's Holford who assumes that analysis.
22 I don't recall specifically. But such an analysis was
23 done. And, actually, I see that on page 6.

24 Q So page 6 of Holford's report?

25 A Page 6 of Holford's, correct.

1 Q When you read that, did you go back and look
2 at any of the source materials upon which he based
3 that analysis?

4 A I'm sorry. But I've already said I did not
5 do any primary data analysis.

6 Q Okay. Do you remember reading testimony of
7 Mark Albrecht where he testified that the -- there
8 would be no significant difference in the infection
9 rate in the period -- the five-month period within the
10 Bair Hugger study compared to the seven-month period
11 of the HotDog study when antibiotics and
12 thromboprophylaxis were identical? You do remember
13 that?

14 A I -- I don't remember the specific details of
15 Albrecht's testimony.

16 Q Just generally do you remember any testimony
17 of Mr. Albrecht that suggested or -- or agreed that if
18 you eliminated antibiotics with thromboprophylaxis, by
19 comparing the identical regimens there was no
20 statistically significant difference?

21 A I -- you know, again, I did not review the
22 Albrecht materials recently enough to give an answer
23 to that question.

24 Q Okay. Well, when you read Dr. Holford's
25 analysis where he demonstrated that the -- that the

1 infection rates were virtually identical, the relative
2 risk of one, did that -- did you look at that and say,
3 "Gee, Holford is just wrong"?

4 A Well, I guess -- I guess a couple of
5 comments.

6 I mean, one -- one would be that clearly the
7 comparison would have a very wide confidence interval
8 around it, whatever they -- whatever the estimate was,
9 which was what I said. That's the price of
10 stratifying the data and taking only a -- a -- a
11 portion of it.

12 And, you know, there's still this a priori
13 question about the case that can be made for
14 confounding by the -- by the antibiotic and
15 thromboprophylaxis regimens.

16 Q What would you consider a wide confidence
17 interval?

18 A I -- again, this is like other -- other terms
19 that I use. I -- I will -- I will just say I don't
20 have rules.

21 But with three events and four events in two
22 groups, I'm sure it calculated and provided the
23 confidence intervals. It would be substantial. It's
24 wide. Any -- any word you want. But they would be --
25 it -- it would cover a broad interval.

1 Q What was the -- the recorded confidence
 2 interval for the relative risk in the McGovern paper
 3 which you would consider to be a wide confidence
 4 interval?

5 A Again, I'm going to refresh my memory --

6 Q Yeah.

7 A -- as to what it was.

8 (Witness reviewing document.)

9 THE WITNESS: 1.2 to 12.5. I certainly
 10 would not describe it as narrow.

11 BY MR. GORDON:

12 Q Okay. Well, do you characterize that as a
 13 wide confidence interval?

14 A I -- again, I don't have particular rules. I
 15 mean, I think it's -- it's a substantial interval
 16 covered by 1.2 to 12.5.

17 Q And the fact that it didn't dip below one,
 18 that was important to you?

19 A Well, that -- that indicates that the .05
 20 level is actually this, yeah.

21 Q Now, we were -- I'm sorry. I got diverted.
 22 We were talking about strength and association and the
 23 impact that that has on whether you could conclude
 24 that confounding was unlikely.

25 And you said that 3.8 moderately strong

1 strength of association, that allowed you to conclude
 2 that such confounding was not only unlikely but not
 3 supported by the evidence.

4 What I want to know is, Numerically how low
 5 would it have to go before you can say "You know,
 6 that's" -- "that's in that" -- "in that zone where I'm
 7 not so sure the odds ratio for relative risk in and of
 8 itself is particularly useful one way or the other in
 9 assessing whether there's a" -- "there's an impact of
 10 confounding"?

11 A Well, there's no -- I can't say there's a
 12 specific quantitative rule or principle. It would
 13 really depend on the strength or the potential
 14 confounders as risk factors themselves.

15 Q You were critical in your report and critical
 16 of many publications of the efforts of the tobacco
 17 industry to discredit the various observational
 18 studies that initially linked to -- cigarette smoking
 19 to cancer; correct?

20 A I've commented on that, correct.

21 Q And -- and specific -- specifically one of
 22 your criticisms is the tobacco industry tried to
 23 create doubt by suggesting there may be unknown
 24 confounders that -- that are causing the difference in
 25 the -- the odds ratios that are coming out in the

1 various observational studies; right?

2 A I've written that kind of statement, correct.

3 Q And the studies upon which the initial
 4 conclusions about cigarette smoking and lung cancer
 5 were drawn in the surgeon general's report, those were
 6 based on, among other things, animal studies and other
 7 things, twenty-nine different observational studies;
 8 right?

9 A I'm sorry. Which report are you referring
 10 to?

11 Q The 1964 surgeon general's report.

12 A That may be the number. There were seven or
 13 nine observation -- cohort studies and another
 14 twenty-something case studies.

15 Q And with respect to men and lung cancer in
 16 moderate to heavy smokers, every single one of them
 17 had a strength association with at least nine. One
 18 was high -- I believe it was somewhat higher than
 19 twenty and thirty.

20 Right?

21 A There were very strong associations, that is
 22 true.

23 Q Those were very strong associations; right?

24 A Strong. Yes, very strong.

25 Q Much stronger than 3.8; right?

1 A 12 is bigger than 3.8.

2 Q Well, in terms of taking those -- those very
 3 high odds ratios across literally dozens of studies
 4 and saying "You know what, those" -- "in three
 5 different" -- "in three different countries, those" --
 6 "those odds ratios are so strong and so consistent,
 7 that that pretty much excludes the possibility of" --
 8 "of some unknown confounder that the tobacco industry
 9 was trying to suggest might be in play," that makes
 10 perfect epidemiological sense, doesn't it?

11 A It just makes perfect common sense, but yes.

12 Q But taking one observational study that
 13 concludes there's a 3.8 odds ratio and concluding that
 14 that odds -- that that odds ratio was sufficient to --
 15 to exclude the possibility of a confounder -- one or
 16 more confounders, that -- that doesn't stand on -- in
 17 the same solid scientific domain as we were just
 18 talking about with respect to cigarette and lung
 19 cancer studies; right?

20 MS. CONLIN: Objection as to form.

21 THE WITNESS: If I can comment. The
 22 tobacco situation is unique in terms of the
 23 strength of association of smoking with lung
 24 cancer.

25 The matter of confounding is something

Page 82

1 that's looked at study by study. First
 2 off, confounding is the property of a particular
 3 data set because of the potential confounders that
 4 are there.

5 So my -- my comment is in reference to
 6 this particular study. It's the one at hand.

7 BY MR. GORDON:

8 Q Well, would you agree with me that -- that
 9 particularly medical science is -- is replete with
 10 individual observational studies that showed some
 11 strong association that was later demonstrated through
 12 robust prospective randomized clinical trials and
 13 multiple epidemiological studies to have been
 14 erroneous?

15 A Not sure "erroneous" is the right word. The
 16 question is, Are there false positive, if you will,
 17 findings that don't hold up on replication? The
 18 answer is yes.

19 Q You are familiar with the Nurses' Health
 20 Study; right?

21 A I am.

22 Q Were there a number of -- actually, well over
 23 a thousand published papers that went back and tried
 24 to find associations between various things and
 25 various outcomes based on the data compiled in the

Page 83

1 Nurses' Health Study; right?

2 A There were many papers in the Nurses' Health
 3 Study.

4 Q Have you ever seen any analysis of how
 5 initial findings from the Nurses' Health Study held up
 6 under subsequent scrutiny with additional studies?

7 A I -- (coughing.) Excuse me. I do recall
 8 seeing -- a paper that I saw in the last three or four
 9 or five years.

10 Q And what's your recollection about the
 11 conclusions of that, the paper that you saw? Did
 12 those initial findings in the various papers by and
 13 large hold up to further scrutiny when they were
 14 replicated or subjected to more robust clinical
 15 trials?

16 A So I don't remember all the details, again,
 17 of this paper. I think the general intent of the
 18 paper was to take some of the associations observed in
 19 the Nurses' Health Study and follow up and look at
 20 what was observed in clinical trials.

21 And I know -- I know that the general message
 22 was that some of them had not held up. And I don't
 23 remember the quantitative details of that paper.

24 Q There was quite a few, wasn't there? It
 25 wasn't just a couple -- a couple here and there didn't

Page 84

1 hold up. But overall they -- they -- everyone --

2 A I just would have to see the paper again to
 3 comment on that.

4 Q Well, let's -- let's talk about one specific
 5 finding, then, that I think you're pretty familiar
 6 with. The -- based on the data from the Nurses'
 7 Health Study, there was a pretty strong consensus in
 8 the medical community that hormone replacement therapy
 9 was a good thing for postmenopausal -- for
 10 postmenopausal women; right?

11 A That's a question that I wouldn't answer
 12 simply yes or no. It had some adverse effects and
 13 some potentially beneficial effects.

14 MR. GORDON: I'm going to show you what
 15 I've marked as Samet Exhibit 4. I will represent
 16 to you that this is a partial printout of the 2004
 17 surgeon general's report on consequences of
 18 smoking, at least a partial. I didn't want to
 19 destroy a forest of trees.

20 (The aforementioned document was
 21 marked Exhibit 4 for identification
 22 by the reporter.)

23 BY MR. GORDON:

24 Q But you were -- you were involved in this
 25 report, were you not?

Page 85

1 A I was the senior scientific editor.

2 Q And in particular, the -- the section that is
 3 the -- in the introduction in Chapter 1 on approach to
 4 causal inference, you -- you would have had a
 5 significant involvement in the drafting of that
 6 section; correct?

7 A I was one of the authors of it.

8 Q Okay. Now, if you -- page -- turn to
 9 page 19 --

10 (Witness turning to page.)

11 BY MR. GORDON:

12 Q -- and the discussion of judgment in causal
 13 inference. You and your co-authors wrote -- this is
 14 in the second full paragraph on the right-hand side of
 15 the page. (Reading):

16 "Properly designed studies
 17 provide a scientific basis for
 18 inferring what the outcome of the
 19 counter-factual state would be, and
 20 permit related uncertain" --
 21 "uncertainty to be properly
 22 quantified."
 23 Right?

24 A That's what it says.

25 Q And you certainly agree with that today;

<p>1 right?</p> <p>2 A Yes, I do.</p> <p>3 Q You go on to say (reading):</p> <p>4 "But in observational studies</p> <p>5 of humans, scientists must try to</p> <p>6 infer what the outcome would be in</p> <p>7 a counterfactual state by studying</p> <p>8 another group of persons who, at</p> <p>9 least on average, are substantively</p> <p>10 different in only one relevant</p> <p>11 variable, the exposure under</p> <p>12 study."</p> <p>13 Is -- you -- that's something you still</p> <p>14 agree with; right?</p> <p>15 A I do.</p> <p>16 Q Now, you discuss the challenges of doing</p> <p>17 randomized assignments under certain circumstances.</p> <p>18 And at the bottom, you start to say</p> <p>19 (reading):</p> <p>20 "In the absence of a randomized</p> <p>21 assignment of exposure, two groups</p> <p>22 may differ on average in more</p> <p>23 factors than just the variable of</p> <p>24 interest. If these other factors</p> <p>25 affect outcome, then their effects</p>	<p>1 can combine with the causal effect</p> <p>2 of the factor of interest, biasing</p> <p>3 the measured effect of that factor.</p> <p>4 These ancillary causes are called</p> <p>5 confounders."</p> <p>6 Right?</p> <p>7 A Correct.</p> <p>8 Q You certainly still agree with that?</p> <p>9 A I do.</p> <p>10 Q You go on to say (reading):</p> <p>11 "As an example of a</p> <p>12 confound" -- "An example of a</p> <p>13 confounding factor might be a</p> <p>14 characteristic associated both with</p> <p>15 taking a medication and</p> <p>16 cardiovascular risk, which appears</p> <p>17 to be the current situation with</p> <p>18 hormone replacement therapy (HRT)</p> <p>19 in women. The observational</p> <p>20 studies showed a clearer</p> <p>21 cardiovascular benefit from HRT</p> <p>22 than did a large randomized trial,</p> <p>23 suggesting that there may be some</p> <p>24 cardioprotective characteristics or</p> <p>25 behaviors of women who voluntarily</p>
<p>1 take HRT that are at least partly</p> <p>2 responsible for the apparent</p> <p>3 benefit of HRT in the observational</p> <p>4 studies."</p> <p>5 Citing Hulley and Blumenthal.</p> <p>6 Continuing (reading):</p> <p>7 "In fact, the results of the</p> <p>8 Women's Health Initiative Trial of</p> <p>9 HRT showed increased risk for</p> <p>10 cardiovascular disease incidence in</p> <p>11 women randomized to HRT."</p> <p>12 Citing Pradhan. (Reading):</p> <p>13 "Confounding by</p> <p>14 cardioprotective characteristics</p> <p>15 associated with taking HRT may have</p> <p>16 obscured these unanticipated</p> <p>17 con- -- "this unanticipated</p> <p>18 consequence of HRT in the</p> <p>19 observational studies."</p> <p>20 Could you translate that for those of us</p> <p>21 who aren't epidemiologists what you were talking</p> <p>22 about here with respect to hormone replacement</p> <p>23 theory -- therapy and the observational studies</p> <p>24 and the cardioprotective characteristics.</p> <p>25 A Sorry. Do you want a translation --</p>	<p>1 Q Yes.</p> <p>2 A -- or a lecture or --</p> <p>3 Q Well --</p> <p>4 A I mean --</p> <p>5 Q I'm not an epidemiologist, but correct me if</p> <p>6 I'm wrong. The observational studies based on a lot</p> <p>7 of data, very big numbers of participants in high</p> <p>8 power, in the nurses' study showed that HRT, hormone</p> <p>9 replacement therapy, had clear cardiovascular benefits</p> <p>10 to when -- when it was -- a randomized clinical trial</p> <p>11 was done with a broader cohort of -- of women than</p> <p>12 just nurses, not only did it not -- did those -- did</p> <p>13 that trial and other subsequent trials not show a</p> <p>14 benefit, it showed that it actually increased the risk</p> <p>15 of cardiovascular disease; right?</p> <p>16 A That's the results of the WHI, the Women's</p> <p>17 Health Initiative, correct.</p> <p>18 Q Well, and when you were talking about</p> <p>19 confounding by cardioprotective characteristics, you</p> <p>20 were talking about the fact that you were looking at a</p> <p>21 group that are -- whoever was looking at the nurses'</p> <p>22 study was looking a group that had characteristics</p> <p>23 that were not translatable to -- to a -- to a broader</p> <p>24 cross-section of -- of all women; right?</p> <p>25 A Sorry. Maybe I'll try to say this like it</p>

<p style="text-align: center;">Page 90</p> <p>1 is.</p> <p>2 The issue here was that women in the</p> <p>3 observational studies who ended up on hormone</p> <p>4 replacement therapy differed in some ways. Their</p> <p>5 report for cardiovascular risk was -- who did not.</p> <p>6 It was not a matter of the general legibility</p> <p>7 of the nurses, but the difference within the nurses or</p> <p>8 some other studies at the time between those on HRT</p> <p>9 who were not assigned randomly but who took it versus</p> <p>10 those who did not.</p> <p>11 Q Well, I'm not sure I understand, and that's</p> <p>12 my problem.</p> <p>13 The initial observational studies showed a</p> <p>14 clear benefit from HRT; right?</p> <p>15 A For cardiovascular disease.</p> <p>16 Q For cardiovascular, correct.</p> <p>17 A Right.</p> <p>18 Q But in subsequent randomized clinical trials,</p> <p>19 not only was there not that, but there was a</p> <p>20 detriment -- a statistically significant detriment in</p> <p>21 cardiovascular disease; right?</p> <p>22 A There was an increased risk for</p> <p>23 cardiovascular events, yes.</p> <p>24 Q Would you agree that there -- there -- that's</p> <p>25 not an isolated example in the history of medicine</p>	<p style="text-align: center;">Page 91</p> <p>1 where -- where an initial approach to some therapeutic</p> <p>2 intervention was perceived as being either positive</p> <p>3 or -- or negative based on one or more observational</p> <p>4 studies that on attempts of replication and/or more</p> <p>5 focused randomized clinical trials did not prove to be</p> <p>6 accurate?</p> <p>7 A I think I said before that not all</p> <p>8 observational studies with findings that purport to</p> <p>9 show associations are replicated.</p> <p>10 Q Wouldn't you agree that a single</p> <p>11 observational study is without replication generally a</p> <p>12 weak basis for drawing definitive causal conclusions?</p> <p>13 A I think a -- the observational study, the</p> <p>14 findings need to be interpreted in light of what is</p> <p>15 known about the association with regard to coherent</p> <p>16 plausibility and -- and so on.</p> <p>17 Q Well, one of the criteria that suggested that</p> <p>18 was used by the surgeon general's report and that you</p> <p>19 yourself discuss is consistency; right?</p> <p>20 A Yes.</p> <p>21 Q And that's important because one study may</p> <p>22 not have gotten it right. But it -- the more studies</p> <p>23 you have that came -- that come to the same</p> <p>24 conclusion, the more likely it is that the conclusion</p> <p>25 is correct and not an outlier result of some bias, a</p>
<p style="text-align: center;">Page 92</p> <p>1 result of some unaccounted for confounder, or</p> <p>2 something like that; right?</p> <p>3 A Well, having multiple studies with similar</p> <p>4 findings adds to the confidence in -- in the findings,</p> <p>5 correct.</p> <p>6 Q Okay. Well, you go on to say in this 2004</p> <p>7 report that (reading):</p> <p>8 "If confounders are recognized</p> <p>9 and their effects measured, these</p> <p>10 effects can often be statistically</p> <p>11 minimized or removed by the</p> <p>12 analysis of a study. However, if a</p> <p>13 confounder is poorly measured, or</p> <p>14 its effects poorly characterized,</p> <p>15 then its effects cannot be</p> <p>16 controlled for in the analysis</p> <p>17 phase of a study, resulting in a</p> <p>18 causal effect that is distorted or</p> <p>19 confounded by the unwanted factor.</p> <p>20 The most extreme version of this</p> <p>21 phenomenon occurs with unmeasured</p> <p>22 confounding, causal factors that</p> <p>23 are not measured at all and whose</p> <p>24 effects are therefore not</p> <p>25 controllable, which can result in</p>	<p style="text-align: center;">Page 93</p> <p>1 biased estimates and underestimates</p> <p>2 of uncertainty, because standard</p> <p>3 analyses implicitly assume an</p> <p>4 absence of confounding from all</p> <p>5 unmeasured factors."</p> <p>6 Did I read that right?</p> <p>7 A You did.</p> <p>8 Q And you still agree with that; right?</p> <p>9 A Yes.</p> <p>10 Q And the only potential confounders that you</p> <p>11 even considered for the McGovern study in rendering</p> <p>12 your opinion were antibiotics and thromboprophylaxis?</p> <p>13 A Well, again, as I said, with this interrupted</p> <p>14 time series design -- excuse me -- design, there would</p> <p>15 have to be other factors that were linked to a time</p> <p>16 period that fit the definition of confounders. And I</p> <p>17 just don't have any basis for suggesting what they</p> <p>18 might be.</p> <p>19 Q Did you do anything to try and determine if</p> <p>20 there were potential confounders --</p> <p>21 A I --</p> <p>22 Q -- besides the two that you looked at?</p> <p>23 A Again, these -- my -- my judgments are based</p> <p>24 on the information and the materials used.</p> <p>25 Q And you didn't do the analysis where you</p>

Page 94

1 isolated the Bair Hugger period where the antibiotics
 2 and the thromboprophylaxis were the same as in the
 3 HotDog period.

4 But do you have any reason today to disagree
 5 with Professor Holford, Mr. Albrecht, Dr. Reed, and
 6 Dr. McGovern that when you compare those two time
 7 periods completely eliminating the potential for
 8 thromboprophylaxis and antibiotics to be different,
 9 there is no difference in the rate of infection?

10 MS. CONLIN: Objection; it assumes facts
 11 not in evidence.

12 THE WITNESS: Again, I think I commented
 13 on this.

14 One is I'm not sure on an observational
 15 basis why these two factors would be kind of
 16 considered as independent risk factors.

17 And, second, yes, I have seen the Holford
 18 analysis and understand what is there.

19 BY MR. GORDON:

20 Q Let's talk about the antibiotics.

21 Do you recall what the --

22 MS. CONLIN: We're at like 1:15. So.

23 MR. GORDON: Do you want to break now?

24 MS. CONLIN: No, it's up to you. But I
 25 know he wants to eat at some point. So I don't

Page 95

1 want you to get into --

2 THE WITNESS: Actually, a break time
 3 would be good.

4 MS. CONLIN: Do you mind?

5 MR. GORDON: That's fine.

6 THE VIDEOGRAPHER: The time is 1:15 p.m.
 7 We are off the record.

8 (At the hour of 1:15 p.m., a
 9 luncheon recess was taken; the
 10 deposition resumed at 1:50 p.m.)

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Page 96

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Page 97

1 LOS ANGELES, CALIFORNIA; TUESDAY, JULY 11, 2017

2 1:50 P.M.

3 -0o0-

4 ***

5 JONATHAN SAMET, M.D.,
 6 having been previously administered an
 7 oath in accordance with CCP 2094, was
 8 examined and testified as follows:

9 ***

10 EXAMINATION (Resumed)

11 THE VIDEOGRAPHER: We are back on the
 12 record. The time is 1:50 p.m.

13 BY MR. GORDON:

14 Q Dr. Samet, I'd like to talk about
 15 antibiotics.

16 There -- do you recall there were two
 17 different antibiotic protocols during the McGovern
 18 interrupted time series that we were discussing;
 19 right?

20 A Correct. Yes.

21 Q Do you remember what they were?

22 A Gentamicin and gentamicin plus teicoplanin.

23 Q Okay. And the HotDog only cohort received
 24 the gentamicin-teicoplanin combination for all the --
 25 the HotDog cohort period; right?

Page 98

1 A Yes.
 2 Q And with the Bair Hugger period, some
 3 received gentamicin only and some received gentamicin
 4 plus teicoplanin; right?
 5 A Correct.
 6 Q Now there's no antibiotic that is universally
 7 effective against every bacteria; right?
 8 A In general, that's true, yes.
 9 Q Do you know of any antibiotic that you would
 10 describe as effective against all bacteria?
 11 A Not at this point, no.
 12 Q Okay. What is gentamicin effective against?
 13 A Primarily gram-negative organisms.
 14 Q Is it effective against -- looking back in
 15 the 2008-2010 time frame, was -- was gentamicin
 16 effective against Staph Aureus?
 17 A It would not be a first line drug for
 18 Staph Aureus.
 19 Q How about if it was negative to staph?
 20 A I actually, don't recall the spectrum of
 21 gentamicin for such staph. But it's certainly not
 22 a -- a drug that comes to mind for a gram-positive
 23 organism.
 24 Q What's -- what is teicoplanin effective
 25 against?

Page 99

1 A It's primarily directed to gram-positives.
 2 Q And somebody did a study and compared one
 3 cohort that had only gentamicin and another cohort
 4 that only had -- only had teicoplanin.
 5 And somebody in the gentamicin -- or several
 6 people in the gentamicin group developed a
 7 gram-positive infection. And few or none developed --
 8 in the teicoplanin group developed a gram-positive
 9 infection.
 10 And you just looked at gram-positive
 11 infections and did the odds ratio, and you found that
 12 if you just had gentamicin, you had a much, much, much
 13 higher odds -- relative risk or attributable risk of
 14 getting a gram-positive infection than if you -- than
 15 if you were being treated with gen- -- teicoplanin.
 16 That's -- that's a hypothetical that I'm
 17 going to set up for you. Okay?
 18 A Okay.
 19 Q In that hypothetical, no matter how high the
 20 relative risk or the attributable risk that you
 21 compared it to, you wouldn't opine that gentamicin
 22 caused the gram-positive infection in people who
 23 received gentamicin only, would you?
 24 MS. CONLIN: Objection; it calls for
 25 speculation.

Page 100

1 You may answer.
 2 THE WITNESS: I -- I would not consider
 3 an antibiotic as a cause for infection, if that's
 4 the question.
 5 BY MR. GORDON:
 6 Q Well, but if gentamicin doesn't treat
 7 gram-positives and somebody getting only gentamicin
 8 gets a gram-positive infection, even if the relative
 9 risk is a hundred versus teicoplanin, you wouldn't say
 10 that there -- that gentamicin caused it; right?
 11 A No, that's correct.
 12 Q You -- you --
 13 A That's how -- that's how I answered it.
 14 Correct.
 15 Q You would say -- you would say in terms of
 16 relative efficacy, gentamicin was relatively much less
 17 effective against gram-positives than teicoplanin;
 18 right?
 19 A Or teicoplanin plus gentamicin, which is the
 20 comparison you offered in your hypothetical.
 21 Q Okay. And the only data upon which you base
 22 your opinion is a head-to-head comparison between two
 23 different warming modalities; right?
 24 A Sorry?
 25 MS. CONLIN: Objection --

Page 101

1 BY MR. GORDON:
 2 Q The only difference -- the only study --
 3 strike that.
 4 The only data on which you base your opinion
 5 is just a head-to-head comparison between two
 6 different types of warming modalities forced-air
 7 warming and convective [sic] blankets; correct?
 8 MS. CONLIN: Objection as to --
 9 BY MR. GORDON:
 10 Q Conductive blankets.
 11 A I'm sorry. I think my expert report covers a
 12 lot more ground than a single study.
 13 Q Okay. Well, there are -- are there any data
 14 upon which you rely that compared Bair Hugger to
 15 nothing?
 16 A The -- the observational data that I examined
 17 was the McGovern study in my March 30 report.
 18 Q And that compares one warming modality to
 19 another; right?
 20 A That's correct.
 21 Q Would you agree that at most, even if
 22 ultimately it's determined that that study is -- is
 23 valid and the conclusions were not confounded by
 24 anything, it really is forced-air warming versus
 25 the -- the blanket, you can't conclude that the Bair

<p style="text-align: center;">Page 102</p> <p>1 Hugger is causing infections. It's just not as 2 effective as the other warming device in preventing 3 them; right?</p> <p>4 MS. CONLIN: Objection as to form.</p> <p>5 THE WITNESS: I think that's a rather 6 different interpretation of the evidence than I 7 have offered.</p> <p>8 BY MR. GORDON:</p> <p>9 Q I agree.</p> <p>10 I'm asking you, If you're comparing two 11 different modalities that are therapeutic 12 intervention, the -- the -- among the purposes of 13 which includes infection reduction, if one is more 14 effective in reducing infections than the other, you 15 can't conclude that the one that isn't quite as 16 effective is causing the infection; right?</p> <p>17 A Well --</p> <p>18 MS. CONLIN: Objection as to --</p> <p>19 THE WITNESS: -- again, my -- my 20 interpretation of the findings in the McGovern 21 study is based on the other evidence I cited in 22 the report, which had to do with the other 23 consequences of having the Bair Hugger in the 24 operating room.</p> <p>25 ///</p>	<p style="text-align: center;">Page 103</p> <p>1 BY MR. GORDON:</p> <p>2 Q Well, is there any reason why those 3 consequences would differ from the Wansbeck General 4 Hospital in Northumbria to all other hospitals in 5 England?</p> <p>6 A Sorry. I just don't understand the question.</p> <p>7 Q Can you think of any reason why the one -- 8 the way the Bair Hugger performs in the Wansbeck 9 General Hospital would be different than the way the 10 Bair Hugger performs in other hospitals throughout 11 England?</p> <p>12 A I don't really have a basis for answering the 13 question.</p> <p>14 I mean, if your question is the 15 generalizability from one hospital to another in 16 England a priori, I don't have sufficient 17 understanding of how hospitals may -- might -- might 18 differ across England, which I think is what you base 19 the question. I assume that operating rooms are to an 20 extent comparable and perhaps different in some ways.</p> <p>21 Q When you read Dr. Holford's report, did you 22 read his analysis of the infection rates, reporting of 23 the McGovern study at Wansbeck General Hospital as 24 how -- as how they compare to reported rates from 25 hospitals throughout the -- the English National</p>
<p style="text-align: center;">Page 104</p> <p>1 Health system?</p> <p>2 A I saw the distribution of infection rates 3 that Dr. Holford had in his report.</p> <p>4 Q Did you do any independent research to see if 5 the -- the numbers that Professor Holford used and 6 calculated were -- were accurate?</p> <p>7 A I don't know about accurate. I think one -- 8 one question is whether the numbers were generated in 9 different ways.</p> <p>10 At least per McGovern, an active surveillance 11 system was implemented in 2008 at Wansbeck. And I'm 12 not sure that the actual -- of the deep joint 13 infections was comparable at the other hospitals that 14 Holford looked at.</p> <p>15 Q Did you do any research to see if it was or 16 wasn't?</p> <p>17 A I'm not sure what research I could have -- 18 could have done. I -- I do know that there was an 19 effort -- an active effort at Wansbeck to address 20 infections, and they implemented a two-person 21 proactive -- active surveillance system.</p> <p>22 Q Do you know anything about the policies and 23 requirements of the National Health Service in England 24 for hospitals to report infections after knee and hip 25 surgeries?</p>	<p style="text-align: center;">Page 105</p> <p>1 A My reading of what is included in these 2 materials was that it was previously once a quarter 3 and that Wansbeck implemented this active surveillance 4 system in 2008. Now, what other hospitals might have 5 done in that regard, I don't know.</p> <p>6 Q So if -- whether other hospitals that used a 7 Bair Hugger reported four quarters throughout this 8 period of time or not, you have no idea; is that 9 correct?</p> <p>10 A Well, I think the question is whether they 11 had similarly proactive surveillance. And that, I 12 can't answer.</p> <p>13 Q Well, one of the reasons that people first 14 started suspecting that there might be a linkage 15 between cigarette smoking and cancer was that prior to 16 the beginning of the twentieth century the rate of 17 lung cancer was fairly low, and starting somewhere in 18 the early part of the twentieth century it started to 19 rise very dramatically; right?</p> <p>20 A Well --</p> <p>21 Q I know I'm not using epidemiologic terms.</p> <p>22 A -- to be -- to be fair and accurate, there 23 were reports from clinicians of rising lung cancer 24 rates that would cause mortality. That wasn't really 25 tracked in the United States until the thirties.</p>

<p style="text-align: center;">Page 106</p> <p>1 Q At some point along the way, somebody got the 2 idea that, hey, there seems -- there seems to be a lot 3 more lung cancer than there used to be; right? 4 A A number of people came to that conclusion. 5 Q And it seemed to be coincident with the rise 6 in popularity of cigarettes; right? 7 A That was one of the hypotheses. 8 Q And that's a hypothesis that ultimately 9 proved to be the case; right? 10 A Correct. 11 Q Obviously, that's not an epidemiological 12 study. But looking at big numbers like that, gee, 13 there's been a steep rise in -- in lung cancer. 14 There's been a steep rise in cigarette usage. Maybe 15 there's a linkage. 16 That -- that's at least one sort of check on 17 the -- the validity and the reliability of 18 observational studies; right? 19 A I'm not sure it's a check. It might be part 20 of the evidence considered under coherence of what is 21 relevant. 22 Q Okay. So would you -- would you consider 23 that to be part of coherence? Right? 24 A Yes. 25 Q Okay. Well, if the Bair Hugger has an</p>	<p style="text-align: center;">Page 107</p> <p>1 attributable risk of 73 percent, wouldn't you expect 2 that hospitals using the Bair Hugger would have higher 3 rates of infection than the Wansbeck Hospital had 4 after they switched to the Bair Hugger -- to the 5 HotDog? 6 A I think that's a -- a -- a question that -- I 7 actually in my expert report talk about that kind of 8 investigation and the potential limitations of doing 9 both, what would be highlights with an ecological 10 study of the hospital where the unit of analysis and 11 that kind of comparison was -- was made. I'm not sure 12 it's a very, if you will, sensitive design. 13 Q Would you -- would -- would a demonstration 14 that hospitals doing active surveillance reporting 15 four quarters that used the Bair Hugger have 16 consistently lower rate of deep joint infections than 17 Wansbeck General achieved after it switched to Hot -- 18 to HotDog -- that that fact alone is something that 19 would at least give you some pause as to whether 20 the -- the findings of McGovern have any 21 transferability outside of the Wansbeck circumstances? 22 A So in this hypothetical, I -- I think the 23 generalizability results from Wansbeck would depend 24 on -- other hospitals in England would depend on 25 whether the surveillance was the same.</p>
<p style="text-align: center;">Page 108</p> <p>1 And -- you know, and I don't know whether 2 there's something particular about Wansbeck, if more 3 difficult cases end up there or not, so... 4 But I -- I think if your question is in this 5 hypothetical -- I just couldn't go much further in 6 interpreting what you found, what you suggested. 7 Q Well, you've -- you've concluded that the 8 Bair Hugger is a substantial contributing cause 9 because it has a 73 percent attributable risk based on 10 the 3.8 relative risk found in McGovern; right? 11 A Correct. 12 Q And you're opining for all these cases, more 13 than 2,000 now in the United States where people had 14 their surgeries performed in dozens -- hundreds of 15 different hospitals throughout the United States. 16 Your -- your opinion is that you could take 17 that finding in Wansbeck and transfer it to all these 18 hospitals throughout the United States and say, yep, 19 it's the Bair Hugger 73 percent of the time. 20 A Well, I -- I think in that -- in that regard, 21 it's useful. But there's now a second report that is 22 from the United States hospitals that essentially has 23 a very similar quantitative estimate of the risk of 24 the Bair Hugger. 25 Q Are you aware that the -- well, strike that.</p>	<p style="text-align: center;">Page 109</p> <p>1 Did you take a look at the individual 2 hospital numbers in that Augustine study that you -- 3 A I'm -- I'm aware there are variations in the 4 risk estimates across the three hospitals, yes. 5 Q And you're aware that one hospital dominates 6 and accounts for more than half of the cases, and that 7 without that hospital in there, there would be no 8 significant results? 9 A You know, again, I'm aware there's 10 heterogeneity by these hosp- -- three hospitals. 11 Q Are you aware that that hospital has publicly 12 said there are many factors that resulted in our 13 reduction in infection rates, and we do not agree that 14 the switch from Bair Hugger to HotDog was the reason 15 for the decline in infection rates? 16 MS. CONLIN: Objection; it assumes facts 17 not in evidence. 18 THE WITNESS: Yeah, I'm not -- I'm not 19 aware of what's been said in that regard. 20 BY MR. GORDON: 21 Q Are you aware that that hospital has -- has 22 disavowed Scott Augustine's use of data he obtained 23 from them? 24 A I -- I have no such knowledge. 25 Q Would it have any impact in your -- your</p>

<p style="text-align: center;">Page 110</p> <p>1 consideration of the reliability of 2 Scott Augustine's -- 3 A I think -- 4 Q -- publication? 5 A -- I have some deeper understanding of why 6 the hospital made that statement. 7 Q By the way, when you -- when you submitted 8 your various papers to publications, are you generally 9 required to provide the publication with two names of 10 potential reviewers? 11 A Generally, no. 12 Q Have you -- are you aware of any publication 13 that you've ever submitted to that required you to 14 submit the names of two potential reviewers? 15 A I -- I couldn't answer that. I've submitted 16 to so many journals. Some -- sometimes they may ask 17 for appropriate reviewers required. I've just -- I 18 don't think I've had that experience. But I can't 19 attest to the hundreds of journals that I probably 20 submitted to at this point in my career. 21 Q Does that strike you as kind of an unusual 22 requirement, to require an author to identify 23 reviewers? 24 A In my experience, it's not -- it's not that 25 frequent for me, in my view.</p>	<p style="text-align: center;">Page 111</p> <p>1 Q In -- in your experience, typically how long 2 does it take to -- for the review process to work? 3 A It's highly variable. 4 Q What's -- what's the confidence interval? 5 What's the shortest period you've experienced and the 6 longest period? 7 A I'm sorry. I -- I wish -- I wish I could 8 answer. I will say -- let me just say that, you know, 9 on average, it's a couple months from submission to 10 getting back, you know, initial comments from an 11 editor. 12 Q How about from initial submission to actual 13 acceptance for publication? 14 A It depends on what's asked for in the 15 revisions. I mean, I certainly had papers that have 16 taken months to do revisions and reanalyses and other 17 things. And sometimes it's very quick. It really 18 depends on what's called for. 19 Q When you say "quick," how -- how quick is 20 quick? What's the -- 21 A Oh, if it's minor revisions, it might be sent 22 back within a several weeks and have an accepted 23 manuscript. 24 Q When you said you noticed the -- that there 25 were two different dates in the Augustine paper when</p>
<p style="text-align: center;">Page 112</p> <p>1 it was accepted for publication -- or when it was 2 submitted and when it was accepted, did you count the 3 number of days in between? 4 A No. 5 Q Would it surprise you if I -- if you were to 6 find out there were forty days in between submission 7 and acceptance and those forty days included Christmas 8 and New Year's? 9 A I'm not sure I'm surprised. It's on the -- 10 on the briefer end of the time -- time duration I 11 discussed. 12 Q That would be pretty quick for -- for the 13 conscientious peer review process to work its way 14 through in your experience; right? 15 A Oh, I -- I think that's highly variable. And 16 I will say it's a brief -- brief manuscript with 17 relatively, you know, limited presentation of data. 18 So perhaps it was done quickly. 19 Q Let's go back to antibiotics. You -- you 20 said that gentamicin was not the first line drug for 21 Staph Aureus. 22 What did -- what did you mean by that? 23 A Well, again, that typically Staph Aureus 24 would be treated with other types of antibiotics 25 besides gentamicin, which -- which -- in my</p>	<p style="text-align: center;">Page 113</p> <p>1 experience, which is now admittedly in the past, was 2 used for gram-negative infections primarily. 3 Q Okay. When you looked at -- strike that. 4 The McGovern analysis is based on aggregate 5 infection data; right? Total numbers of infections of 6 any type? 7 A Yes. 8 Q Nowhere in the McGovern paper itself is there 9 any breakdown in the types of infections that were 10 occurring from the two different periods; right? 11 A That's correct from my recollection, yes. 12 Q But you had available to you at least the 13 specific bacterial infections that all which were 14 listed in Exhibit 16 to the McGovern deposition, which 15 you did list as one of the things you reviewed; right? 16 A I don't recall specifically that type of 17 infection was included in what I've seen as the 18 primary data, so I can't comment on that. 19 Q Did -- did you look at the types of 20 infections? 21 A No. 22 Q Were you curious? 23 A Was I curious about -- I'm not sure I 24 understood that the data were there. 25 Q Okay. So you -- you concluded the -- the</p>

<p style="text-align: center;">Page 114</p> <p>1 change in antibiotics had no impact on the overall 2 infection; right? That was one of the -- one of the 3 conclusions; right?</p> <p>4 A I concluded that it was not a confounding 5 factor, correct.</p> <p>6 Q How many Staph Aureus cases were there in the 7 HotDog cohort?</p> <p>8 A I said I've not looked specifically at the 9 breakdown of infections by organisms.</p> <p>10 Q Would it surprise you to learn that there 11 were zero Staph Aureus infections in the HotDog only 12 cohort?</p> <p>13 A I don't know about surprise. I take that as 14 what it is. I mean --</p> <p>15 Q Well, would it surprise you to learn that 16 almost a third of the infections in the Bair Hugger 17 only cohort were Staph Aureus?</p> <p>18 A Really the same answer.</p> <p>19 Q Well, would you agree that if you look at the 20 overall infection rates when they stayed the same, 21 that doesn't tell you if the antibiotics which is a 22 confounder with respect to specific infections like 23 Staph Aureus?</p> <p>24 MS. CONLIN: Objection as to form.</p> <p>25 THE WITNESS: Sorry. Can -- can you</p>	<p style="text-align: center;">Page 115</p> <p>1 repeat.</p> <p>2 BY MR. GORDON:</p> <p>3 Q If you're using an -- a drug like gentamicin 4 that is ineffective against Staph Aureus and during 5 the time that you're using gentamicin only you have a 6 few Staph Aureus cases and after you switch to adding 7 teicoplanin, which is effective against Staph Aureus, 8 your -- and the number of Staph Aureus cases goes 9 down -- in fact, in the case of the HotDog only 10 period, it drops to zero -- would you agree that the 11 question of whether the antibiotic change had -- it 12 was a confounder while it may not reflect -- be 13 reflected in the overall numbers, it certainly is 14 worth looking into whether it might have been a 15 confounder with respect to Staph Aureus infections?</p> <p>16 A Well, I -- I would be surprised if the data 17 were -- were robust enough given the sample size of 18 the infections to explore specific infectious 19 organisms.</p> <p>20 But I understand the genesis of the question. 21 But I think it would be, with the data at hand, very 22 hard to address.</p> <p>23 Q Well, so if an intervention is made for the 24 purpose of a specific type of organism and there is a 25 decline in those organisms, but other organisms don't</p>
<p style="text-align: center;">Page 116</p> <p>1 decline or maybe even go higher, your analysis of 2 whether that intervention with respect to that 3 specific organism has any confounding would be that 4 no, because the -- you know, the overall rate is the 5 same, forget about what it -- what it did -- for what 6 it was supposed to do, that's -- your view is that 7 that wasn't -- that that's not a confounder?</p> <p>8 A No, I -- I didn't -- I didn't say that. I -- 9 I think it's a little hard to have -- have this 10 discussion without actually having a better 11 understanding of the rate of staph infection in the 12 Bair Hugger period and in the conductive warming 13 period.</p> <p>14 Q Which you didn't analyze?</p> <p>15 A I said I did not.</p> <p>16 Q Did you see that Dr. Wenzel did when you read 17 his report?</p> <p>18 A I don't recall specifically Wenzel's report, 19 but...</p> <p>20 Q Do you recall reading in Dr. Reed's 21 deposition that the Wansbeck Hospital or the Family 22 Trust instituted screening for methicillin-susceptible 23 Staph Aureus in January 2010?</p> <p>24 A I recall that they implemented a program, I 25 think, with nasal spray and so on.</p>	<p style="text-align: center;">Page 117</p> <p>1 Q Not just screening. It was also 2 decolonization of positive --</p> <p>3 A Correct.</p> <p>4 Q -- strains?</p> <p>5 MS. CONLIN: Objection; it assumes facts 6 not in evidence.</p> <p>7 BY MR. GORDON:</p> <p>8 Q Well, do you recall reading Dr. Reed's 9 testimony where he said that --</p> <p>10 A Well, I -- I do. I do recall the story.</p> <p>11 Q Did you look at the number of Staph -- 12 Staph Aureus cases before and after MRSA screening was 13 implemented?</p> <p>14 A No, I did not.</p> <p>15 Q And again you got Staph Aureus happening 16 during the Bair Hugger only period when it was 17 gentamicin and no MRSA screening. And in the HotDog 18 period you have no Staph Aureus after this had been 19 implemented and the addition teicoplanin and MRSA 20 screening.</p> <p>21 And your opinion is that that doesn't matter 22 because the overall rates, that's all that matters?</p> <p>23 A That's not my opinion. I'm not sure how you 24 got to that.</p> <p>25 Q Well, if the number of Staph Aureus cases in</p>

<p style="text-align: center;">Page 118</p> <p>1 the HotDog only period was zero, all of the -- well, 2 strike that.</p> <p>3 If the vast majority of the Staph Aureus 4 cases that occurred in the HotDog period occurred 5 prior to the time that both teicoplanin and MRSA 6 screening was implemented and no Staph Aureus cases 7 occurred during the HotDog period after the MRSA 8 screening and teicoplanin were implemented, would you 9 still be able to rule out teicoplanin and MRSA 10 screening as having any confounding impact on 11 infection rates?</p> <p>12 A Well, I think you said the key thing, which 13 is infection rates in the observation period for 14 conductive warming is shorter than that for forced-air 15 warming.</p> <p>16 I just would have to look at the data to see 17 what the expectation was coming from the gentamicin as 18 to how many cases you might expect. There's a small 19 numbers issue here.</p> <p>20 Q If -- if somebody did an observational study 21 and compared smokers and nonsmokers and looked at all 22 cancers as an end point, it turns out that, gee, in 23 the smoker group there's a much higher incidence of 24 lung cancer, but in the nonsmoker group there's 25 several incidents of melanoma, brain cancer, perhaps</p>	<p style="text-align: center;">Page 119</p> <p>1 some other things that I think you'd agree were not -- 2 have never been associated with cigarette smoking, but 3 the overall incidence of cancer was pretty comparable, 4 would you think that observational study would be a 5 valid study for saying, hey, smoking doesn't cause 6 cancer?</p> <p>7 A I'm not sure -- sorry. I just -- if I can 8 restate what I think I heard you say. There's a study 9 of smokers and nonsmokers.</p> <p>10 And in the smokers, there's a large number of 11 lung cancer cases observed?</p> <p>12 Q If you just look at lung cancer, there's an 13 increased -- a substantial increased relative risk 14 compared to the nonsmokers.</p> <p>15 A Uh-huh.</p> <p>16 Q But if you look at all cancers, because the 17 nonsmoker group in my hypothetical has melanomas and 18 brain cancers, the overall incidence of cancer rate 19 renders it not -- the difference not statistically 20 significant, would you conclude from that that smoking 21 doesn't cause cancer?</p> <p>22 A Again, I'm -- this is a hypothetical 23 hypothetical. And I'm -- if you're saying that an 24 outcome is a composite and it includes some cancer 25 specifically related to smoking among others -- I</p>
<p style="text-align: center;">Page 120</p> <p>1 think that's what I heard.</p> <p>2 Q Yeah. An aggregate. All cancers.</p> <p>3 A Well, I -- I mean, again, I -- I will say if 4 the analogy is to looking at all infections, I don't 5 think there's an organism-specific question here 6 related to Bair Hugger that it only causes one kind of 7 bacterial infection.</p> <p>8 Q But you decided there's no organism-specific 9 question related to any of the other interventions 10 that -- that the Wansbeck Hospital took prior to the 11 switch to HotDog; right?</p> <p>12 A I'm sorry. Can you repeat that again.</p> <p>13 Q You -- you said that there's -- you're not 14 aware of any organism-specific issue related to Bair 15 Hugger. I'm not asking about the Bair Hugger.</p> <p>16 I'm asking about the interventions that 17 Wansbeck General Hospital took in an effort -- in a 18 series of efforts to reduce their extremely high 19 infection rates, some -- some of which were targeted 20 at specific types of organisms.</p> <p>21 But you're saying that there's no 22 organism-specific issue there that you need to look 23 at; right?</p> <p>24 A I was saying that the data for overall 25 infection in the face -- in fact, as -- as you</p>	<p style="text-align: center;">Page 121</p> <p>1 mentioned, some interventions that might have lower 2 infections, it was still -- the -- the magnitude of 3 the increase was still substantial. I don't quite 4 understand this.</p> <p>5 Q The magnitude of the increase was still 6 substantial just disregarding whether particular types 7 of infections had increased or decreased.</p> <p>8 Is that what you're saying?</p> <p>9 MS. CONLIN: Objection as to form.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: And, again, I've not seen 12 analyses, unless I'm missing them, of the actual 13 rates of different types of infections in the -- 14 in the two periods. And if such exist, they would 15 be compromised by numbers.</p> <p>16 BY MR. GORDON:</p> <p>17 Q Let's talk about that number, the 3.8.</p> <p>18 How is that amount computed?</p> <p>19 A It's computed as the -- it's computed as the 20 odds ratio, as I recall -- let me just pull it up and 21 make sure I'm right --</p> <p>22 Q Yeah. Yeah.</p> <p>23 A -- of the -- of the rates and the two time 24 periods of deep joint infection.</p> <p>25 Q And the rates are based on the number of</p>

<p>Page 122</p> <p>1 infections in the reported surveillance period divided 2 by total number of procedures performed during the 3 period; right?</p> <p>4 A Correct.</p> <p>5 Q And in the McGovern paper, what was the rate 6 for the HotDog only period?</p> <p>7 (Witness reviewing document.)</p> <p>8 THE WITNESS: I --</p> <p>9 BY MR. GORDON:</p> <p>10 Q If it's taking too long, it's on page 5042.</p> <p>11 A 0.8.</p> <p>12 Q And that's based on how many -- 13 How -- how is that 0.8 derived?</p> <p>14 A That is 3 over 268.</p> <p>15 Q Okay. What was the rate for the HotDog only 16 period?</p> <p>17 A I'm sorry. That's -- that was the HotDog 18 period.</p> <p>19 Q I'm sorry. I misspoke.</p> <p>20 What was the rate during the Bair Hugger 21 period?</p> <p>22 A 3.0.</p> <p>23 Q 3.0?</p> <p>24 A That's correct.</p> <p>25 Q Okay. And what was the -- what were the --</p>	<p>Page 123</p> <p>1 What was the equation that --</p> <p>2 A Well, it's 32 over 1,034.</p> <p>3 Q Okay. And so tell me how -- how the 4 calculation gets to 3.1.</p> <p>5 A Oh, it's calculated -- it's the odds ratio 6 divided by 2. --</p> <p>7 Q I -- I misspoke. 3.8; right? The average 8 that you're using is 3.8; right?</p> <p>9 A Correct.</p> <p>10 Q Divide that 3 percent -- or 3.0 by 0.8; 11 right?</p> <p>12 A No. It's the odds ratio from the table.</p> <p>13 Q Well, how -- how was that -- that 3.8 odds 14 ratio derived?</p> <p>15 A There's an underlying 2x2 table with warming 16 device, yes/no; infection, yes/no. And then it's 17 calculated as the odds ratio from the table.</p> <p>18 Q But I'm just trying to understand, What -- 19 what are the numbers that are plugged in?</p> <p>20 A The numbers are the -- sure. The numbers are 21 the 321034 and the 3368.</p> <p>22 Q Well, is -- is there any relationship between 23 3.0 and 0.8 in terms of coming up with the odds ratio?</p> <p>24 A The -- are you asking for how an object was 25 calculated?</p>
<p>Page 124</p> <p>1 Q Yeah.</p> <p>2 A So it is -- it comes out of the table that 3 describes. And it's simply the cross-product of the 4 diagonals.</p> <p>5 Q Does it have anything to do with the ratio of 6 3.0 to 0.8?</p> <p>7 A Well, the same -- the same numbers are -- the 8 same numbers are involved, yes.</p> <p>9 Q And that if that -- if the -- for example, if 10 the 0.8 number were higher, the odds ratio would go 11 down, wouldn't it?</p> <p>12 A It would be a different data set, but yes.</p> <p>13 Q Okay. Well, do you recall when you read 14 Dr. Reed's testimony that he said that there was -- 15 that the numbers weren't quite correct, there was 16 actually one more infection in each group?</p> <p>17 A I'm aware of that discussion, yes.</p> <p>18 Q Well, were you aware of it before you wrote 19 your report?</p> <p>20 A I don't think I was.</p> <p>21 Q Okay. So you're aware of it now?</p> <p>22 A I'm aware of it now.</p> <p>23 Q You became aware of it because you read 24 Dr. Holford's report?</p> <p>25 A I -- probably Holford's report brought my</p>	<p>Page 125</p> <p>1 attention to it.</p> <p>2 Q So you hadn't read -- either hadn't read it 3 or just --</p> <p>4 A I -- you know, again, I -- I remember some 5 discussion about data sets. And I don't know what is 6 the, quote, "correct" -- "correct data set." But I'm 7 aware that Reed commented about the data.</p> <p>8 Q Okay. If you add one infection to each 9 group, what happens to the odds ratio?</p> <p>10 A That's -- you know, again, I mean, that's not 11 a question that could be answered generically. I 12 mean, if we calculate it here, I suspect that since 3 13 is a very small number, adding 1 to make it 4 would 14 lower the odds ratio.</p> <p>15 Q Well, why don't you take a look at 16 Dr. Holford's report here.</p> <p>17 Is that Exhibit 4?</p> <p>18 MS. CONLIN: Exhibit 3.</p> <p>19 BY MR. GORDON:</p> <p>20 Q 3. And if you'll look at page 3, Footnote 1. (Witness turning to page.)</p> <p>22 BY MR. GORDON:</p> <p>23 Q For the moment, I don't want to ask you about 24 Dr. Holford's calculation based on his analysis of the 25 data set and the -- all the other things. He's</p>

Page 126

1 just -- Footnote 1 is just based on Dr. Reed's
 2 testimony that was one more infection in each group.

3 Do you have any reason to think that
 4 Professor Holford screwed up the calculations that he
 5 did there?

6 A Oh, he certainly did the calculations
 7 correctly.

8 Q Okay. And assuming those --

9 Well, first of all, do you have any reason to
 10 think that Dr. Reed testified inaccurately?

11 A I can't comment on that.

12 Q Okay. Well, if -- if -- if that testimony is
 13 accurate and Dr. Holford's calculations are accurate,
 14 the odds ratio would be 2.86; right?

15 A According to the calculation shown here, yes.

16 Q And the confidence interval would be 1.03 to
 17 8.33; right?

18 A As described here, yes.

19 Q Is that -- would you say that's a strong
 20 association or moderately strong association, one that
 21 would allow you to feel comfortable in saying there
 22 couldn't be any confounders that can account for this
 23 odds ratio?

24 A My only comment is 2.86 is lower than 3. --
 25 3.8.

Page 127

1 Q And a confidence interval that starts at 1.03
 2 is just barely meaningful; right?

3 A I don't think meaningful is determined by the
 4 confidence level. Perhaps as significant as 3.05 is,
 5 but meaningful, no.

6 Q Okay. But your report was predicated on the
 7 assumption that the odds ratio of 3.8 was accurately
 8 reported in the McGovern paper; right?

9 A It was based on a report in a peer reviewed
 10 paper, correct.

11 Q Okay. And based on the testimony of Dr. Reed
 12 at least -- and there are -- and -- and there are
 13 other documents that Dr. Holford refers to that
 14 corroborate at least his -- his point about there
 15 being one more in -- in HotDog -- based on that and
 16 the calculations, the -- this -- the odds ratio is at
 17 best 2.86; right?

18 A Well, in this -- in this recalculation adding
 19 one more event to each group, it's 2.86, correct.

20 Q Does that give you any pause that adding one
 21 more infection to each group causes the odds ratio to
 22 go from 3.8 to 2.86?

23 A I don't know about giving any pause. But
 24 I've commented before that these events are not -- are
 25 not so common. So it's not surprising that the odds

Page 128

1 ratio would drop with the addition of one event to the
 2 HotDog period when there's very few events there.

3 MR. GORDON: What number are we on? 5.
 4 Let me show you what's been marked as Exhibit 5.
 5 This was previously part of -- of the McGovern
 6 exhibits, which did not have unique exhibit
 7 numbers for a multiseries of pages.

8 (The aforementioned document was
 9 marked Exhibit 5 for identification
 10 by the reporter.)

11 BY MR. GORDON:

12 Q But you did indicate that you had available
 13 to you the McGovern testimony and the McGovern
 14 exhibits, and there was some discussion -- there was
 15 some testimony about this.

16 Do you recall seeing this, Exhibit 5, prior
 17 to today?

18 A I think I've seen this.

19 Is this the sixty-day moving average data?

20 Q No. That would be Professor Holford's
 21 report. This is --

22 MS. CONLIN: This is Exhibit 21 from the
 23 McGovern deposition.

24 THE WITNESS: Okay.

25 ///

Page 129

1 BY MR. GORDON:

2 Q Well, let me see if this helps refresh your
 3 recollection. Why don't you -- you know what,
 4 Ms. Conlin pointed out to me before we just broke that
 5 I had marked an exhibit from Mr. Albrecht's deposition
 6 where there was actually writing on it from
 7 Mr. Albrecht. So I didn't copy that.

8 MR. GORDON: So this one, I want you to
 9 have a copy available to you -- to you. So I'm
 10 going to give you Exhibit 6. I will hand you
 11 Exhibit 6, which is the same McGovern paper we've
 12 been talking about, but it just has no writing on
 13 it the way the one in ours did.

14 (The aforementioned document was
 15 marked Exhibit 6 for identification
 16 by the reporter.)

17 BY MR. GORDON:

18 Q And I would like you on Exhibit 6 to turn to
 19 Figure 7, which appears on page 1843.

20 (Witness turning to page.)

21 BY MR. GORDON:

22 Q Does this refresh -- refresh your
 23 recollection as to whether you saw Exhibit 5, this
 24 version of Figure 7 where the infection rate is
 25 reflected as a -- as a moving average as opposed to

<p style="text-align: center;">Page 130</p> <p>1 a -- a uniform average across the entire Bair Hugger 2 period?</p> <p>3 A I'm not sure that that -- at this -- at this 4 point, I've seen some of the Holford moving average 5 figure as -- well, I -- I do think I've seen this 6 figure before, and I think I remembered the comment 7 about the, quote, "jittering" in the -- indicate the 8 points.</p> <p>9 Q I -- the jittering came from Albrecht's 10 testimony.</p> <p>11 A Okay. Well, as I said --</p> <p>12 Q And -- and the -- and the reason I want to 13 be -- I want to clarify is that Mr. Albrecht did 14 testify about -- about Figure 7 as it was published, 15 but at the time of his deposition, we didn't have 16 what's been marked as Exhibit 5. We only got that 17 afterwards. We got that from McGovern. So the 18 only -- the only person who would have testified about 19 it is -- is Mr. McGovern -- Dr. McGovern.</p> <p>20 So I don't want to -- there was -- you're 21 right, there was testimony from Mr. Albrecht about 22 jittering. It wasn't in connection with Figure 7. It 23 wasn't in connection with Exhibit 5.</p> <p>24 A Okay.</p> <p>25 Q So whether you've seen Exhibit 5 before or</p>	<p style="text-align: center;">Page 131</p> <p>1 not, looking at --</p> <p>2 MS. CONLIN: He said he has seen it 3 before.</p> <p>4 BY MR. GORDON:</p> <p>5 Q And I'm saying whether you have or you 6 haven't. I --</p> <p>7 MS. CONLIN: Well, object to the form of 8 the question then.</p> <p>9 MR. GORDON: Okay.</p> <p>10 Q My -- my point is my question is not going to 11 depend on whether you've seen it previous to today. 12 So I'm not -- that's not where -- where I'm going with 13 this.</p> <p>14 Would -- in your view as an expert in 15 epidemiology, does Figure 7 as published convey a -- a 16 more useful and more accurate picture for the reader 17 than Figure 7 as reflected in Exhibit 5?</p> <p>18 A I guess there are a couple of comments. I 19 probably need more information about what Exhibit 5 20 comprises. It says a moving average. I'm not sure of 21 the window.</p> <p>22 I assume this is Wansbeck. The numbers 23 are -- 1290 is not what you would get by adding up 24 what is in Table 2 of the McGovern paper, so I'm not 25 quite sure what Exhibit 5 portrays.</p>
<p style="text-align: center;">Page 132</p> <p>1 Q Well, in fact, if you look at the start date 2 on Exhibit 5, it starts September 2008; right?</p> <p>3 A Yes, it does.</p> <p>4 Q Whereas what they published actually starts 5 in July of 2008; right?</p> <p>6 A Correct.</p> <p>7 MR. GORDON: Now, let me show you 8 Exhibit 7. And this too is included in the large 9 McGovern exhibits, whether you -- you saw it or 10 not.</p> <p>11 (The aforementioned document was 12 marked Exhibit 7 for identification 13 by the reporter.)</p> <p>14 BY MR. GORDON:</p> <p>15 Q I guess the question, that you recall -- you 16 recall seeing this before?</p> <p>17 A I'm sorry. Would you --</p> <p>18 Q Have you seen this before, Exhibit 7?</p> <p>19 A I think I've seen this.</p> <p>20 Q Do you recall any testimony about email where 21 Mr. Albrecht was telling Reed and McGovern, 22 Scott Augustine, and Christopher Nachtsheim (reading): 23 "Barely made it with the new 24 sampling numbers"?</p> <p>25 A I -- yeah, perhaps I'm just simply not sure.</p>	<p style="text-align: center;">Page 133</p> <p>1 Q Okay. Do you recall reading a portion of the 2 email where Mr. Albrecht says (reading):</p> <p>3 "Okay. We made it here to a 4 significant difference, so I'll 5 update the manuscript to reflect 6 the new infection numbers."</p> <p>7 Do you recall reading that before?</p> <p>8 A I -- I may have. Frankly, I'm just not sure 9 I did. Whether -- you know, again, I -- looking -- 10 looking through so much materials, but I'm just not 11 sure.</p> <p>12 Q When you do epidemiological studies, do you 13 wait until you gather enough data to show -- you make 14 it to a statistical significance?</p> <p>15 MS. CONLIN: Objection as to form.</p> <p>16 THE WITNESS: The only comment I'd make 17 is typically there would be a protocol that would 18 dictate that, like -- like the data collection.</p> <p>19 BY MR. GORDON:</p> <p>20 Q Did you see the protocol for the McGovern 21 paper?</p> <p>22 A The underlying protocol for study.</p> <p>23 Q Do you know if one even exists?</p> <p>24 A I can't comment on that.</p> <p>25 Q So in terms of the start date, do you have</p>

<p>Page 134</p> <p>1 any idea when they started looking at the data, what 2 start date -- whether there was a start date that was 3 pre-chosen?</p> <p>4 A My understanding of the start date is that it 5 corresponded approximately, I think, to the 6 implementation of the surveillance system.</p> <p>7 Q Well, now I want you to go back -- again, 8 we're comparing Exhibit 5 to the published version of 9 Figure 7 in Exhibit 6 -- or -- excuse me -- Exhibit 7. 10 There are two different start dates; right? 11 September 2008 and July 2008; right?</p> <p>12 A If you're -- 13 MS. CONLIN: Objection as to form. 14 THE WITNESS: Your question is, Is the 15 start -- Is the start date in Exhibit 5 September 16 2008? And that in Exhibit 6 is July 2008. 17 BY MR. GORDON: 18 Q Oh, it -- I'm sorry. I misspoke. It is 19 Exhibit 6. 20 Okay. So now let's go to Professor Holford's 21 moving chart that we've been talking about, which I 22 believe it appears on page -- you'll find it on 23 page 13 of his report. 24 (Witness turning to page.) 25 ///</p>	<p>Page 135</p> <p>1 BY MR. GORDON: 2 Q So first of all, what's your understanding of 3 what this chart on page 13 of Professor Holford's 4 report depicts? 5 A Well, I need a minute to go back and reread 6 this -- 7 Q Okay. 8 A -- before I comment. 9 (Witness reviewing document.) 10 THE WITNESS: Okay. 11 BY MR. GORDON: 12 Q What's your understanding of what this chart 13 depicts? 14 A My understanding is that this chart depicts 15 values for a chi-square calculated on a 2x2 table that 16 involves different starting points for the period over 17 which events are counted for the Bair Hugger device. 18 Q Okay. And the -- that red line, what does 19 that -- what does that reflect? 20 A That's the value that the chi-square 21 specifically needs to obtain the statistically 22 significant -- less than .05. 23 Q So based on this chart, a start date of -- 24 would a start date of 7/1/2008 be above or below the 25 cutoff for statistical significance?</p>
<p>Page 136</p> <p>1 A Well, it looks like it would be slightly 2 above. 3 Q Okay. And if you -- if the start date was 4 August 30, 2008, would it be above or below? 5 A That particular value would be -- well, I 6 think it's reflecting the somewhat, you know, variable 7 numbers and the fact that these infections are not 8 very common. But it would be below. 9 Q Okay. 10 MR. GORDON: We have 9 -- 8. I'll show 11 you what's been marked as Exhibit 8, a document 12 entitled "Infection Graph." It's part of the 13 McGovern exhibits. 14 (The aforementioned document was 15 marked Exhibit 8 for identification 16 by the reporter.) 17 BY MR. GORDON: 18 Q Do you recall seeing this before? 19 A I -- not specifically, no. 20 Q What I want to draw your attention to in 21 particular is the statement in Mr. Albrecht's email to 22 Dr. Reed. He says in the second sentence (reading): 23 "For example, in the first data 24 file you sent me, there were a 25 total of N equals 4,263 surgeries</p>	<p>Page 137</p> <p>1 from 10/1/07 to 10/30/2010. In the 2 second date" -- "data set, the 3 dates are unlisted and there are N 4 equals 4,444" -- "63 surgeries. 5 These totals do not match." 6 Do you see that? 7 A I do. 8 Q Okay. Now you testified earlier that you had 9 seen a data set -- 10 MR. GORDON: I'm going to mark as 11 Exhibit 9 what has been previously marked as 12 Albrecht Exhibit 10. 13 (The aforementioned document was 14 marked Exhibit 9 for identification 15 by the reporter.) 16 BY MR. GORDON: 17 Q My question to you is, Does this appear to be 18 the data set that you're referring to that you saw 19 after you wrote the report relative -- relative to -- 20 A I think -- the comment on here making it thus 21 far similar to a large spreadsheet like this. 22 Q Okay. Well, what's the start date on 23 Exhibit 9? 24 A It's October 1, 2007. 25 Q Okay. And that's the start date of what</p>

Page 138	Page 139
<p>1 Mr. Albrecht says to Dr. Reed was in the first data 2 file that he sent from Reed to Albrecht; right? 3 A Correct. 4 Q If you use that data set based on 5 Dr. Holford's -- Holford's graph, if you were to start 6 the data analysis in October of 2007, would it have 7 been statistically significant? 8 A Which date? 9 Q October 1 of 2007. 10 A Until -- until somewhere in 2008, none of the 11 high score values are above the red line. 12 Q Yeah. 13 To cut to the chase, the only way, using the 14 data starting in October 1, 2007 -- the only way you 15 get the statistical significance is if you lop off the 16 first nine months and don't -- don't start until 17 July 1, 2008; right? 18 MS. CONLIN: Object as to form, it 19 misstates the record. 20 THE WITNESS: I mean, my comment is that 21 the -- you know, the line where the high score 22 value is starting in 2007 is not clearly above 23 that section until somewhere around 2008, yes. 24 BY MR. GORDON: 25 Q Yeah. I -- I want to -- ultimately what I</p>	<p>1 want to ask you about is whether in your view this is 2 the appropriate -- the proper way to do a statistical 3 analysis in observational studies. 4 You have data going all the way back to 5 October 1, 2007. At some point, you're contemplating 6 starting your data set in July 2008. You're -- 7 you're -- at some point, you're contemplating starting 8 the data analysis somewhere in 2008. Ultimately, you 9 go with July 2008 as the starting point. 10 And July 2008 just happens to be the first 11 time in this data set that you cross over or, in the 12 words of Mr. Albrecht, "barely make it to statistical 13 significance." 14 And if you did wait until August, it actually 15 dips back under statistical significance, and you'd 16 have to wait until October 2008 to start again. And 17 even then it dips back down in your statistical 18 significance. It doesn't stay permanently above it 19 until -- until the -- early 2009. 20 MS. CONLIN: Objection as to form. 21 THE WITNESS: So what I'm -- 22 MS. CONLIN: No. Hold on. 23 Objection as to form, and I object to the 24 premise of that question to the extent that you're 25 suggesting that the data in 2007 is complete.</p>
<p style="text-align: center;">Page 140</p> <p>1 BY MR. GORDON: 2 Q Dr. Samet, is this the way you do 3 epidemiology? You get your data and see what -- you 4 know, see what you need to -- to use -- 5 MS. CONLIN: The same -- 6 BY MR. GORDON: 7 Q -- to make it -- to make it -- to -- to 8 barely make it to statistical significance? 9 MS. CONLIN: Same objection. Object to 10 premise of the question. 11 THE WITNESS: I -- I mean, to step back, 12 I thought the start date corresponded with the 13 implementation of the surveillance system that 14 went into play. That was in 2008, if I recall 15 correctly. 16 So in terms of when it started, when the 17 surveillance -- when the surveillance started I 18 thought was the starting point may be optimized 19 to -- for the -- for that data. 20 I mean, I think if your general question 21 is when looking at data how it's approached in an 22 analysis, it's usually per protocol. 23 BY MR. GORDON: 24 Q And you have no evidence that there ever was 25 a protocol for this, though; right?</p>	<p style="text-align: center;">Page 141</p> <p>1 A I don't have evidence one way or the other. 2 Q Have you seen any testimony that this was -- 3 the observational component of the study was done 4 after the fact, after they had done the bubble study, 5 and they decided, well, let's take a look and see if 6 we can -- 7 A I don't know about the time the exhibit was 8 published. 9 Q Well, going back to my original premise -- 10 well, I want to clarify something. 11 Your understanding is that some formal 12 surveillance program started in July of 2008? 13 A Somewhere in there. And, again, I might be 14 off. But I thought they identified two surveillance 15 nurses who began an active surveillance program. 16 Governor Reed speaks to this. 17 Q And when do you think that was? 18 A I think it was 2008. 19 Q I'll show you what I've marked as Exhibit 10. 20 (The aforementioned document was 21 marked Exhibit 10 for 22 identification by the reporter.) 23 BY MR. GORDON: 24 Q Have you seen this document before? 25 A I have.</p>

Page 142	Page 143
<p>1 Q When did you first see this? Before or after 2 you wrote -- 3 A After. 4 Q What was it that you -- 5 What -- what caused you to review this 6 afterwards? 7 A I think this was provided by Jan Conlin. 8 Q Okay. 9 MR. GORDON: And I'm going to give you 10 Exhibit 11. And I will represent to you that 11 Exhibit 11 is just a printout of the chart that 12 appears on the second page of Exhibit 10. It's 13 just for me a little bit easier to read. I don't 14 know. Maybe your eyes may be a lot better than 15 mine, but... 16 (The aforementioned document was 17 marked Exhibit 11 for 18 identification by the reporter.) 19 BY MR. GORDON: 20 Q Is this the -- the source of your 21 recollection as to when the surveillance period began? 22 A I actually thought I saw it in either Reed or 23 McGovern's reports or depositions. 24 Q Okay. And your recollection is they would 25 have testified that that began in July of 2008?</p>	<p>1 A Well, as I said, I wasn't sure of the date, 2 but that was my recollection. 3 Q Well, based on what you're seeing here and 4 whatever you're characterizing as the surveillance, 5 the formal surveillance, that wouldn't have taken 6 place until at least December of 2008; right? 7 MS. CONLIN: Objection to form -- 8 THE WITNESS: I'm sorry. 9 MS. CONLIN: -- it misstates the record. 10 (Witness reviewing document.) 11 MS. CONLIN: Is there a question pending? 12 MR. GORDON: Well, I don't know. He was 13 reading, but... 14 THE WITNESS: Trying to read. 15 BY MR. GORDON: 16 Q Well, let -- let me see if we can speed this 17 up. 18 On the first page of Exhibit 10, the 19 right-hand column, first full paragraph says 20 (reading): 21 "In 2008, hospitals were 22 required by the HPA," which is the 23 Health Protection Agency, "to 24 identify and include patients who 25 were readmitted with an SSI, and</p>
<p style="text-align: center;">Page 144</p> <p>1 further emphasis was put on 2 organizations to use the data to 3 evaluate local practice and 4 institute changes that are 5 required." 6 Do you see that? 7 A Yes. 8 Q Okay. If you drop down to the -- to the 9 last -- the last full paragraph on the page, it says 10 (reading): 11 "During the last two quarters 12 of 2008 and 2009, Northumbria 13 Healthcare NHS Foundation Trust was 14 reporting SSI rates in the combined 15 total of surgeries in THR, TKR" -- 16 or total hip and total knee -- "and 17 repair neck of femur between 18 3.5 percent and 5 percent and was 19 regularly receiving letters from 20 the HPA informing the trust of its 21 high outlier status for SSI. 22 "As it was performing 23 approximately 2,200 hip and knee 24 replacements, every year 25 implementing robust surveillance in</p>	<p style="text-align: center;">Page 145</p> <p>1 the SSI became a priority for the 2 orthopedic team and the trust." 3 I'll continue on to the next page, where 4 it says (reading): 5 "Following the correspondence 6 from the HPA requesting action and 7 the attendance of a group of 8 clinical staff at an SSI conference 9 in Birmingham held by Patient 10 Safety First, the SSI group was 11 formed. 12 "A multidisciplinary team 13 formed the trust's SSI group, and 14 the first meeting took place in 15 December 2008. This group was 16 chaired by a proactive orthopedic 17 surgeon and included a consultant, 18 microbiologist, senior managers, 19 infection control leads, matrons, 20 and" -- "matrons, and clinical 21 leads from operating theaters. 22 "Prior to the designated team 23 of surveillance staff, surveillance 24 of the mandatory reporting to the 25 Health Protection Agency, as it was</p>

1 then known, was being completed by
 2 personnel while they were still
 3 doing their regular work. There
 4 was no ownership of the process and
 5 the assurance in the validity of
 6 the results.

7 "The first action point of this
 8 meeting was to place a successful
 9 bid to appointment two full-time
 10 SSI nurses, i.e., twelve months
 11 secondment therefor."

12 Based on what I've just read, if this is
 13 correct, the surveillance -- the formal
 14 surveillance that you're talking about didn't take
 15 place any earlier than December of 2008; correct?

16 MS. CONLIN: Objection as to form, and
 17 it's a misstatement of both this document and his
 18 prior testimony.

19 THE WITNESS: I -- based on what's in
 20 this document, it appears they appointed the two
 21 full-time nurses somewhere after the first
 22 meeting.

23 BY MR. GORDON:

24 Q So whether the surveillance -- well, if --
 25 and -- you're -- you're --

1 Q Fair enough.

2 Do you have any criticisms of
 3 Professor Holford's report? Any points where you
 4 flatly disagree with him?

5 A I -- I think that's a question that's not
 6 answered with a simple yes or no.

7 I understand what Holford has done. And I
 8 think he's clear more or less in his descriptions of
 9 what he has done.

10 And -- and there's also a -- a peer reviewed
 11 publication that as a result has gone through the test
 12 of peer review.

13 Q With Rothman you know that the numbers were
 14 used in the peer reviewed publication were not
 15 accurate; right?

16 MS. CONLIN: Objection; it misstates --

17 THE WITNESS: Well --

18 MS. CONLIN: -- the record.

19 THE WITNESS: -- you know, again, I --
 20 the statement from Dr. Reed and the questions
 21 about the data set, I, frankly, don't know why
 22 there's problems with the data set or why these
 23 issues are being raised.

24 But there's at least one investigator who
 25 said there might be a problem. And I don't know

1 Are you thinking that Dr. Reed or
 2 Dr. McGovern testified differently?

3 A I would have to go back and look.
 4 MS. CONLIN: Well, and as you know,
 5 Mr. Gordon, I think this is highly misleading
 6 because you know Dr. Reed, who you said testified
 7 to a July date, is not at Northumbria. Janet Matt
 8 was the one.

9 MR. GORDON: That wouldn't be a speaking
 10 objection, would it, Ms. Conlin?

11 MS. CONLIN: Well, I -- I think it's
 12 really misleading to do that to a witness.
 13 BY MR. GORDON:

14 Q So whether the -- strike that.

15 You -- you read -- I think you said you read
 16 Dr. Holford's report --

17 A Yes.

18 Q -- in some detail --

19 A Yes.

20 Q -- as opposed to Professor Borak's --

21 A I read both reports.

22 Q Right. But I thought you said you spent a
 23 little more time with -- I don't want -- whatever
 24 words you used. But you --

25 A I think I referred to the Wenzel report.

1 the basis for that statement.

2 BY MR. GORDON:

3 Q It wasn't just one of the investigators, was
 4 it?

5 THE WITNESS: May I have some water?

6 MS. CONLIN: Okay.

7 THE WITNESS: May I have a break?

8 MS. CONLIN: Yeah, we can do -- yeah.

9 Well, are you going to a new area? Can
 10 we take a short break? We've been going now for a
 11 couple of hours.

12 MR. GORDON: Let me finish this up here.

13 Exhibit 12; right? That's 12.

14 (The aforementioned document was
 15 marked Exhibit 12 for
 16 identification by the reporter.)

17 BY MR. GORDON:

18 Q And you might have seen this in the large
 19 McGovern production. But my question is whether you
 20 have -- you recall seeing it before. And in
 21 particular I want to address -- address your attention
 22 to the statement where Mr. Albrecht says to Mike Reed
 23 (reading):

24 "I've done a quick analysis of
 25 the new data, and the trend does

<p style="text-align: center;">Page 150</p> <p>1 persist. But the data files are 2 not totally consistent (in regards 3 to the data the BR JBJS article was 4 based upon.</p> <p>5 "I checked the files 6 side-by-side over the common time 7 periods, and they do not match up 8 for dates, etc. In fact, in the 9 data file you sent me, the 10 infection rate during the 11 forced-air warming period was 12 slightly lower than the previous 13 one.</p> <p>14 "Additionally, there is not a 15 date associated with most 16 infections (just a yes response for 17 about 50 percent of the infected 18 cases). So clipping at sixty days 19 cannot be done.</p> <p>20 "So I'm giving you a graphic 21 for the Wansbeck data, but do not 22 distribute it for a 'slightly' 23 conflicts with the study data due 24 to different reporting practices in 25 your data.</p>	<p>1 "The relevant info supporting 2 the figures of the infection odds 3 ratio FAW to CFW equals 2.98, 4 95 percent confidence level, 1.36 5 to 6.53. P value for this odds 6 ratio is now 0.0062 based upon a 7 wall test."</p> <p>8 And he says (reading): 9 "I'll look at the hip and knee 10 separately next." 11 Have you seen this before?</p> <p>12 A I -- I think so, yes.</p> <p>13 Q And do you recall Mr. Albrecht's testimony 14 about discrepancies in the data set, those used for 15 the publication?</p> <p>16 A At this point specifically -- at this point, 17 again, it would be hard for me to sort out what I've 18 seen and where.</p> <p>19 Q Okay. Let's go back to Dr. --</p> <p>20 MR. GORDON: All right. We'll take a 21 break.</p> <p>22 THE VIDEOGRAPHER: The time is 3:04 p.m. 23 We are off the record.</p> <p>24 (A brief recess was taken.)</p> <p>25 THE VIDEOGRAPHER: We are back on the</p>
<p style="text-align: center;">Page 152</p> <p>1 record. The time is 3:17 p.m. 2 BY MR. GORDON:</p> <p>3 Q Dr. Samet, were you aware before your report 4 that the Laminar [phonetic] flow system in one of 5 operating rooms at Wansbeck that had been 6 malfunctioning had been repaired during the Bair 7 Hugger only period?</p> <p>8 A No, I'm not. I did not.</p> <p>9 Q So, obviously, you couldn't have taken that 10 into consideration in determining --</p> <p>11 A I had no knowledge of that.</p> <p>12 Q Okay. Were you aware that the -- prior to 13 writing your report that they changed the wound 14 dressing used after knee and hip surgeries at Wansbeck 15 during the Bair Hugger only period?</p> <p>16 A I think I became aware of that change 17 afterwards, but perhaps from reading Exhibit 10 or 18 something else.</p> <p>19 Q By "afterwards," you're talking about --</p> <p>20 A After March 30.</p> <p>21 Q Okay. And have you been -- become aware at 22 any time that Dr. Reed has publicly stated that he 23 switched the wound dressings after he ran a study that 24 demonstrated that there was a significant reduction in 25 joint infections with the use of the newer wound</p>	<p style="text-align: center;">Page 153</p> <p>1 dressings?</p> <p>2 MS. CONLIN: Objection; it misstates the 3 record.</p> <p>4 THE WITNESS: I am not aware of 5 Dr. Reed's pronouncements on that.</p> <p>6 BY MR. GORDON:</p> <p>7 Q Okay. And I take it you have done no 8 independent research to -- at this point to see if the 9 wound dressing change could have been a confounding 10 factor?</p> <p>11 A I -- nothing specific, no.</p> <p>12 Q Okay. Do you know --</p> <p>13 Did you know prior to writing your report 14 that they had changed the policy with respect to 15 surgical personnel wearing their own personal shoes 16 and required them to start using dedicated clogs that 17 were left in the OR and washed in the OR?</p> <p>18 A I became aware of some of this -- these 19 procedure changes, again, after the March 30 report.</p> <p>20 Q Would you agree that in terms of infection 21 control, that there are a number of practices that 22 have been developed and -- and implemented over time 23 that individually might not have statistically 24 significant robust evidence to demonstrate that they 25 and they alone have an impact on a positive impact on</p>

<p style="text-align: center;">Page 154</p> <p>1 infection rates, but that when you do a care -- a care 2 bundle, that it's the care bundle, the whole panoply 3 of things, that that can have a significant impact on 4 overall infection rates?</p> <p>5 A That may be true, but I've done no particular 6 relevant assessment of the literature on that topic.</p> <p>7 Q Would you consider yourself an expert in the 8 area of, you know, hospital infection control 9 practices?</p> <p>10 A I think I already replied to a similar 11 question.</p> <p>12 Q It was similar.</p> <p>13 A I said no.</p> <p>14 Q Okay. So whether care bundles that have a 15 whole series of practice changes, whether they impact 16 overall infection rates in hospitals or not, that's 17 beyond your scope of -- of what you're going to be 18 offering an opinion on?</p> <p>19 A Not something that I specifically -- I 20 specifically looked at.</p> <p>21 Q Okay. And I apologize. I -- I'm going to 22 sustain her objection of asked and answered. I was 23 starting to forget.</p> <p>24 Did you know before you wrote your report 25 that the MRSA screening had been implemented?</p>	<p style="text-align: center;">Page 155</p> <p>1 A Oh, I can't recall.</p> <p>2 Q Okay. Have you -- did you review any 3 literature that looked at the impact of prewarming on 4 maintenance of normothermia?</p> <p>5 A Along the way, I've looked at that, and I 6 read the Kurtz paper, among others, trial. Looked -- 7 looked at that issue of warming and prewarming only 8 superficially.</p> <p>9 Q And -- and you mentioned Kurtz. I wonder if 10 you meant Mella [phonetic] on prewarming.</p> <p>11 A No. I was actually thinking about the Kurtz 12 paper. I guess it's not prewarming per se.</p> <p>13 Q And my question was -- and I apologize. 14 What -- what I'm asking you about is -- and your 15 answer presumably would be the same. I just want to 16 be clear.</p> <p>17 Have you done any research into more -- more 18 recent literature as to whether the combination of 19 prewarming and active warming during surgery is more 20 or less or equally efficacious in terms of maintenance 21 of normothermia than just warming during surgery?</p> <p>22 A No, I have not.</p> <p>23 Q So did you know before you wrote your report 24 that when they switched to the Bair Hugger 25 strike -- strike that.</p>
<p style="text-align: center;">Page 156</p> <p>1 Did you know before you wrote your report 2 that when they switched from Bair Hugger to HotDog 3 with the Hot- -- with the implementation of the HotDog 4 at Wansbeck, they also implemented the addition of 5 prewarming?</p> <p>6 A No. I don't know those details, no.</p> <p>7 Q Now, you said you saw Exhibit 10 and the 8 chart in Exhibit 11 after you wrote the report; is 9 that right?</p> <p>10 A Yes.</p> <p>11 Q Now, am I -- I'm correct that you have not 12 looked at any published data from Great Britain or the 13 National Health Service on infection rates at all; 14 right?</p> <p>15 A I don't think so. I may have -- I -- there 16 may have been -- I'm trying to recollect. I may have 17 seen a National Health Service annual report along the 18 way, but I'd have to refresh my memory on that.</p> <p>19 Q Okay. Well, if you look at Exhibit 11, the 20 chart, would you agree with me that the -- the line 21 that shows the SSI percentage for each quarter 22 reflected there is -- there's a -- there's a fair 23 amount of up and down movement?</p> <p>24 A There's some variation of the line, yes.</p> <p>25 Q And if this is accurate, this would indicate</p>	<p style="text-align: center;">Page 157</p> <p>1 that in the second quarter of 2012 their infection 2 rate spiked back up over 3 per- -- over 3 percent; 3 right?</p> <p>4 A Well, the -- the line went up, and there's 5 presumably some instability as -- in these numbers 6 over -- over time. I'm just trying to --</p> <p>7 Sorry. Let me make sure I understand what 8 this line is.</p> <p>9 (Witness reviewing document.)</p> <p>10 BY MR. GORDON:</p> <p>11 Q Yeah. And -- and I don't want to mislead 12 you. This -- this is not just giving knee, although I 13 believe that most of it --</p> <p>14 A Yeah, surgical.</p> <p>15 Q But it includes neck pain -- repair of neck 16 pain.</p> <p>17 A Well, it says surgical site infection. It 18 doesn't say deep joint infection.</p> <p>19 Q Yeah. I guess you have to look at the text 20 and the NHS reporting requirements and I think 21 Dr. Reed's testimony.</p> <p>22 Rather than me looking at Exhibit 11 or 23 actually discussing what that does or doesn't say, 24 based on everything you've seen, wouldn't you agree 25 that the data for joint infection rates throughout the</p>

<p style="text-align: center;">Page 158</p> <p>1 Bair Hugger period was -- had -- had instability, to 2 use your word?</p> <p>3 MS. CONLIN: Objection as to form.</p> <p>4 THE WITNESS: Well, I -- it's variable. 5 I mean, I don't know whether the word is 6 "instability." But the -- the rates that -- the 7 line varies in terms of the number, which is 8 not -- not surprising in terms of a relatively 9 uncommon event.</p> <p>10 BY MR. GORDON:</p> <p>11 Q Given that it's a relatively uncommon event 12 and given that the -- there's the variability that 13 you've described, would you -- doesn't that make it a 14 lot harder to conclude that if you just look at one 15 period and treat it as a monolith in terms of the 16 average infection rate and look at some other period 17 and say whatever difference you see is attributable to 18 one change when there's been a lot of variability and 19 a whole bunch of other changes that could have had 20 impact, you know, on particular types of infections or 21 as a care bundle on overall practices? Wouldn't you 22 agree that that's not proper -- that's not a proper 23 application of epidemiology?</p> <p>24 MS. CONLIN: Objection as to form, it 25 misstates the record.</p>	<p style="text-align: center;">Page 159</p> <p>1 THE WITNESS: I mean, I'm -- yeah, can 2 you help me with what the question is.</p> <p>3 BY MR. GORDON:</p> <p>4 Q Well, when you drafted your opinion, you 5 reviewed the McGovern paper as it was published. You 6 didn't have the benefit of some of data we've gone 7 through. You hadn't read some of the -- the testimony 8 the specifically relates to that testimony.</p> <p>9 Now you -- at this point, you've gone through 10 some things that would demonstrate that there was 11 significant variability, that if you look at the types 12 of infection -- I guess you haven't. I've given you a 13 document to look at that and see if you can do that -- 14 types of infection vary over time.</p> <p>15 The -- and given all these things, do you 16 still believe that -- that proper application of -- of 17 epidemiologic methodology leads inexorably to the 18 conclusion that it's the Bair Hugger and the Bair 19 Hugger alone that just nearly quadruples the infection 20 rate?</p> <p>21 A Well, I think I'm going to answer your 22 question. The way to deal with the variability in 23 small numbers is to take the average across the period 24 of observation. And that's going to be the best 25 estimate of way things usually are.</p>
<p style="text-align: center;">Page 160</p> <p>1 So the fact that -- the somewhat variable 2 estimates of counts, essentially, were averaged. 3 There's what? Thirty-two, thirty-three events across 4 the McGovern Bair Hugger period.</p> <p>5 It's not surprising that there is some -- 6 some variability in this -- in the data. So the best 7 way to try to understand what's happening -- they're 8 reasonable. But to me that is a reasonable average.</p> <p>9 Q So let's go back to Professor Holford's 10 report. And take a look at his page 12, the chart 11 that he identifies as Figure 2.</p> <p>12 (Witness turning to page.)</p> <p>13 BY MR. GORDON:</p> <p>14 Q I think earlier you had made some reference 15 about a two-moth moving average or a sixty-day moving 16 average.</p> <p>17 Is this the -- the chart you were thinking 18 of?</p> <p>19 A That's the figure -- the figure with the 20 sixty-day average, yeah.</p> <p>21 Q Okay. Do you have any quarrel with how 22 Professor Holford has plotted this?</p> <p>23 MS. CONLIN: Objection as to form.</p> <p>24 THE WITNESS: I'm not sure about quarrel.</p> <p>25 I mean, I -- it's clear it states clearly what was</p>	<p style="text-align: center;">Page 161</p> <p>1 done.</p> <p>2 BY MR. GORDON:</p> <p>3 Q Okay. Well, based on everything you know, do 4 you think what he did was erroneous for any reason?</p> <p>5 A I think what he's done is display the average 6 in a line that shows a sixty-day moving window 7 average.</p> <p>8 Q And do you -- when you -- when you take a 9 look at that line, it looks like there are kind of two 10 peaks, one far more pronounced at the very end of the 11 Bair Hugger period; right?</p> <p>12 A Well, this -- yeah, there's some movement in 13 the -- in the -- in the average. It dips, and it goes 14 back up.</p> <p>15 Q Well, from April or mid 2009 when there seems 16 to be a fairly low point in the moving average to the 17 high point in early 2010, that's a -- that's an 18 enormous swing, isn't it?</p> <p>19 A I don't know about enormous. I mean, you 20 know, when we look at these specs, we're going from 21 less than 2 percent up to 4 percent, 4 1/2 percent.</p> <p>22 And, you know, some of this is the intrinsic 23 noisiness of the data, which is why I wanted an 24 average.</p> <p>25 And I -- you know, again, my comment earlier</p>

1 about the surveillance time in Wansbeck, I thought it
 2 started in October '08. I just -- which is why I had
 3 wondered with that -- somewhere in 2008 with the lower
 4 rates earlier in the year.

5 But in any case, I mean, yes, there's some
 6 variation in this moving average.

7 Q And from a statistical standpoint, you're --
 8 you think that the proper way to analyze these data is
 9 to just say "Well, we'll just" -- "we're just going to
 10 compare the overall average of a twenty-month period
 11 that goes up and down and up to a seven-month period"?

12 A No. Let me say --

13 MS. CONLIN: Well, objection -- objection
 14 as to form in terms of the time.

15 THE WITNESS: Sorry. Forgive me. Just
 16 restate the question for me.

17 MR. GORDON: Well, I don't think it was
 18 accurate. So, Jan, if you want to enlighten me as
 19 to where I -- I misspoke I would be happy to --

20 MS. CONLIN: Well, I --

21 MR. GORDON: -- be educated.

22 MS. CONLIN: -- I can't tell from -- I
 23 don't want to have a speaking objection, but I
 24 think --

25 MR. GORDON: I'm inviting you.

1 MS. CONLIN: All right. The -- this
 2 chart starts on September 1st, 2007, which we
 3 think the record is pretty clear. And it's an
 4 inaccurate -- inaccurate data set for that. So
 5 that -- that was the issue, but I didn't want
 6 to --

7 MR. GORDON: Okay. No. I'm glad you --
 8 and that's fine. Let's -- I will clarify --
 9 clarify my question then. I wasn't -- that wasn't
 10 what I was intending to ask.

11 Q I'm talking about the twenty-month period
 12 that is depicted in Professor Holford's Figure 2 as
 13 the Bair Hugger study period. There's a red line
 14 across that corresponds to the study time period
 15 reflected in the McGovern paper. And that's a
 16 seven-month period that is identified here as the
 17 HotDog study. Those are -- are the two periods I was
 18 referring to.

19 And you've got twenty months of -- of data in
 20 the Bair Hugger study that go to a low, as you say,
 21 of, it looks like, less than 1 percent to a high of 4
 22 or 5 percent during that twenty months. And then
 23 you've got -- and that's being compared to the average
 24 of seven months of data from McGovern -- or from the
 25 HotDog period.

1 Do you think from an epidemiological
 2 standpoint that averaging data with that kind of
 3 variability over twenty months and comparing it to a
 4 seven-month period is sound epidemiological
 5 methodology?

6 A Well, yeah, let me comment from a different
 7 perspective. I've done a lot of time series analyses.

8 This data set is simply too small to do any
 9 sort of formal analysis. It's small. It's -- I'll
 10 use the word "noisy." And probably the best way to
 11 get a stable signal is to average the data that is at
 12 hand.

13 Q When you have a small and noisy series,
 14 doesn't that impact the -- the weight that you can
 15 give to any conclusions from it?

16 A Well, again, as I said, the best way to try
 17 to understand what the signal is, is to average all
 18 the data you have and -- and use it all.

19 Q You're saying the best way under adverse --
 20 the -- the less than ideal circumstances of having a
 21 small and noisy data set?

22 A I'm simply referring to the data at hand in
 23 this -- in this picture.

24 Q In your professional work, either your
 25 teaching or if you do health organization bodies like

1 that, would you recommend a change in practice based
 2 upon a single observational study that has this
 3 limited data set and is this noisy?

4 MS. CONLIN: Objection as to form, it
 5 misstates his report.

6 THE WITNESS: Yeah. Again, my
 7 conclusions as I've -- the conclusion of my report
 8 is not based solely on the McGovern data set.
 9 There's extensive review of other materials.
 10 BY MR. GORDON:

11 Q Yeah, and we're going to -- and I -- and I am
 12 confining my questions to McGovern.

13 So if -- if you take had the McGovern paper
 14 out of your consideration, are you saying that your --
 15 your opinion would remain the same, that the Bair
 16 Hugger is a substantial cause of surgical site
 17 infections, substantial to -- or to periprosthetic
 18 infections?

19 MS. CONLIN: It calls for speculation.

20 THE WITNESS: I -- I -- the only comment
 21 I could make is that there's now a second study,
 22 the Augustine report, with another -- an est- --
 23 another estimate of the risks of this too. That's
 24 I think what I can say at this point.

25 ///

<p style="text-align: center;">Page 166</p> <p>1 BY MR. GORDON:</p> <p>2 Q Okay. But what I want to understand is when 3 you came to the opinion that you offered to the court 4 on March 30, as I read the report, it -- the McGovern 5 study is a critical element in how you arrived at your 6 conclusions. But if I'm -- in fact, that's how I read 7 it. That doesn't really matter.</p> <p>8 A Yeah. That's --</p> <p>9 Q My question to you, because you keep talking 10 about it -- it's just part of the data. If you 11 didn't have the Mc --</p> <p>12 If you hadn't had the McGovern paper at all, 13 would you have, based on all the other stuff that 14 you're talking about, arrived at the same conclusion 15 on March 30?</p> <p>16 A The McGovern paper is, at the time I wrote my 17 report, the sole paper in the peer reviewed literature 18 offering an estimate of the risk of deep joint 19 infection associated with the Bair Hugger device.</p> <p>20 Q So if you hadn't had the McGovern paper, you 21 would not have reached the conclusions that you 22 reached --</p> <p>23 MS. CONLIN: It calls for speculation.</p> <p>24 BY MR. GORDON:</p> <p>25 Q -- on March 30; right?</p>	<p style="text-align: center;">Page 167</p> <p>1 MS. CONLIN: It calls for speculation.</p> <p>2 THE WITNESS: I -- I could only -- I 3 could only say that there would not have been 4 anybody to -- absent the McGovern paper, to 5 quantify the magnitude of this.</p> <p>6 BY MR. GORDON:</p> <p>7 Q Okay. But you would have still opined that 8 there was a risk, just you couldn't quantify it?</p> <p>9 A I just can't answer that question.</p> <p>10 Q Well, let's approach it from a different 11 standpoint. You've mentioned now several times that 12 the McGovern paper was not the only evidence or data 13 upon which you based your conclusion.</p> <p>14 Tell me what the other body of -- of data is 15 that contributed to your opinion.</p> <p>16 A Well, let me take out my report --</p> <p>17 Q Sure.</p> <p>18 A -- and -- and comment on that. I think the 19 sections lay out the different lines of evidence that 20 were considered and perhaps --</p> <p>21 Critically the idea is laid out in Figure 3 22 on page 21.</p> <p>23 Q Okay. So table -- that table lists four 24 sentences; right?</p> <p>25 A No. I said Figure 3 on page 21.</p>
<p style="text-align: center;">Page 168</p> <p>1 Q Oh, Figure 3. I'm looking at page 3. 2 I'm sorry. What page?</p> <p>3 A 21.</p> <p>4 Q Okay. Okay. So you -- this is, you say, 5 "Mechanisms by Which the Bair Hugger Increases Risk 6 for Joint Infection"; is that right?</p> <p>7 A That's the title.</p> <p>8 Q And you have the first two arrows. One goes 9 to disturbed unit or directional flow. The other goes 10 to microbial contamination of a surgical field. 11 Right?</p> <p>12 A Correct.</p> <p>13 Q Let's talk about the bottom, microbial 14 contamination of a surgical field.</p> <p>15 What do you mean by "microbial 16 contamination"?</p> <p>17 A Microorganisms.</p> <p>18 Q Okay. And what data did you review that -- 19 well, strike that.</p> <p>20 Am -- am I correct in inferring from your 21 depiction here in Figure 3 that you believe there are 22 some evidence that the Bair Hugger device results in 23 increased microbial contamination of a surgical field?</p> <p>24 A Well, it is shown that -- the -- the 25 literature cited shows that -- and -- and also the</p>	<p style="text-align: center;">Page 169</p> <p>1 computational fluid dynamics of modeling that there's 2 increased flow of particles across the surgical field.</p> <p>3 I believe at least one study -- maybe it's 4 Moretti [phonetic] -- shows increased numbers of 5 microorganisms associated with the Bair Hugger 6 operating and then also the disruption of directional 7 flow. So those contribute to increased risk of 8 infection, which is what I've laid out here in 9 Figure 3.</p> <p>10 Q You -- you referenced computational fluid 11 dynamics.</p> <p>12 I take it you are referring to the 13 computational fluid dynamics analysis that was done 14 under contract to Dr. Al Garbashi [phonetic] at the 15 request of plaintiffs in this case?</p> <p>16 A That's correct.</p> <p>17 Q I noticed --</p> <p>18 MR. GORDON: Let me show you an exhibit 19 I'm up to 13. Let me show you Exhibit 13. 20 (The aforementioned document was 21 marked Exhibit 13 for 22 identification by the reporter.)</p> <p>23 BY MR. GORDON:</p> <p>24 Q I noticed in your reference materials you 25 cited to an unpublished document by Memarzadeh.</p>

<p style="text-align: center;">Page 170</p> <p>1 And I want to know, first of all, Is 2 Exhibit 13 that document to which you were referring? 3 MS. CONLIN: I'm sorry. What's the 4 question? 5 BY MR. GORDON: 6 Q Exhibit 13. And take a look at your report 7 there. On the reference list is a reference to 8 some -- to some unpublished something from Memarzadeh. 9 It's your Reference Number 51. 10 MS. CONLIN: He's just asking you if 11 that -- the reference on there -- 12 THE WITNESS: Well, I assume so. I'm 13 just trying to read from the reference document. 14 BY MR. GORDON: 15 Q This is -- is Exhibit 13 what you listed as 16 Number 51 on your materials considered? 17 A Appears to be the case, yes. 18 Q So this is something you had -- 19 Exhibit 13 is something you had available 20 before you wrote your report; right? 21 A Yes. 22 Q And if you turn to page 10 of Exhibit 13 -- 23 (Witness turning to page.) 24 BY MR. GORDON: 25 Q -- it says (reading):</p>	<p style="text-align: center;">Page 171</p> <p>1 "This investigation validates 2 the results and conclusions drawn 3 by Moretti and others that the 4 forced-air warming technology does 5 not in and of itself result in 6 increased risk of surgical wound 7 infection. 8 "However, this investigation 9 further indicates that if the 10 operating room ventilation system 11 is designed properly, the 12 contaminating particles from staph 13 around the patient will not impinge 14 on the surgical wound due to 15 thermal plume dynamics." 16 So that -- you read that before you 17 rendered your opinion? 18 A (No audible response.) 19 Q And -- and we can go through this. 20 But what this is, is a computational fluid 21 dynamics study; right? 22 A Yes. 23 Q And staying on page 10, you see that under 24 the conflict of interest statement, it says 25 "undeclared"?</p>
<p style="text-align: center;">Page 172</p> <p>1 A I see that, yes. 2 Q The CFD, the computational fluid dynamics, 3 that -- that you referenced in your report -- or that 4 you actually discussed in your report by 5 Dr. Al Garbashi, if that were a published paper, you 6 would -- you would agree he'd have to declare a 7 conflict of interest if that was -- he did that -- he 8 was paid by the plaintiff's counsel to do that for 9 this litigation? 10 A He would have cleared his finances. 11 Q Well, don't you think that would be -- would 12 constitute a conflict of interest? 13 A I -- I think that surmises that funding 14 source influences the outcome of this computational 15 fluid dynamic model. 16 Q Well, okay. Page -- page 10 on the 17 Memarzadeh thing identifies the funding sources of the 18 National Institutes of Health; right? 19 A (No audible response.) 20 Q You have to say yes or no. 21 A It does, yes. 22 Q Okay. But -- so -- and I guess I've seen 23 this a lot where there's a conflict of interest 24 statement and a funding source statement. 25 Is that -- are -- are you saying that there's</p>	<p style="text-align: center;">Page 173</p> <p>1 view there -- if you declare your funding source, 2 that's -- you don't have to declare any conflict of 3 interest? 4 MS. CONLIN: It misstates his testimony. 5 THE WITNESS: No, I didn't say that. 6 BY MR. GORDON: 7 Q Okay. In fact, I -- the opposite is true. 8 Wouldn't you -- wouldn't you agree that it's 9 customary to declare funding sources and to identify 10 any conflicts of interest? 11 A Any potential conflicts of interest, right. 12 Q Do you think being an expert witness hired to 13 testify on behalf of one side in civil litigation in 14 and of itself is a conflict of interest -- a potential 15 conflict of interest that would be -- that would 16 ordinarily be declared? 17 A Well, I -- I think it's clear that the report 18 was done for the plaintiffs. 19 Q You're talking about Dr. Al Garbashi? 20 A Yeah, Dr. Al Garbashi. 21 Q I -- for the record, my -- my point is, if it 22 had been a -- a paper for use beyond this litigation, 23 it would -- you would agree it should probably have a 24 conflict of interest disclosure that it was originally 25 prepared for litigation?</p>

Page 174

1 MS. CONLIN: It calls for speculation.
 2 THE WITNESS: I can't say. Presumably
 3 I'm speculating.
 4 BY MR. GORDON:
 5 Q Okay.
 6 A If he were to have published the paper, he
 7 would have revealed the funding source.
 8 Q In the Memarzadeh paper that you listed as
 9 part of your references, the funding source is the
 10 National Institutes of Health.
 11 What -- what is that organization?
 12 A I'm familiar.
 13 Q I know that sounds -- I don't mean it to
 14 sound sarcastic. I have to ask a basic line of
 15 questions.
 16 A Yes.
 17 Q Tell -- tell me what the National Institutes
 18 of Health are.
 19 A It's a collective set of institutes that
 20 carry out research and fund the researches.
 21 Q Who pays that, to support the National
 22 Institutes of Health?
 23 A Taxpayers.
 24 Q So it's a government-funded entity?
 25 A Largely.

Page 175

1 Q And you've done work funded by grants from
 2 the National Institutes of Health, haven't you?
 3 A Yes.
 4 Q Would you agree that the National -- the
 5 purpose of the National Institutes of Health is to
 6 objectively try to do and fund research for the
 7 improvement of the public health?
 8 A Well, improvement of health generally, yes.
 9 Q Okay. The National Institutes of Health is
 10 not involved in litigation.
 11 The reason for -- for what it does has
 12 nothing to do with trying to help one side or another
 13 in litigation that prevail in court; right?
 14 A Correct.
 15 Q And do you know Farhad Memarzadeh?
 16 A No.
 17 Q Did you -- how did you come to be in
 18 possession of a copy of Exhibit 13?
 19 A I really can't say sitting here right now.
 20 Q Well, why is it that you chose to discuss the
 21 findings of a hired expert working for the plaintiffs
 22 in your report, but you said nothing in your report
 23 about findings of the computational fluid dynamics
 24 carried out by and fund -- by an employee of and
 25 funded by the National Institutes of Health?

Page 176

1 A Well, frankly, I was impressed by the scope
 2 and elegance of the modeling done by --
 3 How do you pronounce his name?
 4 MS. CONLIN: Dr. Al Garbashi.
 5 THE WITNESS: Dr. Al --
 6 MS. CONLIN: Al Garbashi.
 7 THE WITNESS: Al Garbashi. And, you
 8 know, I'm not in a position to specifically
 9 compare this analysis with the other, except that
 10 I will say that the other was -- Dr. Al Garbashi's
 11 was I -- I think far more intensive than the scope
 12 and computational approach.
 13 And I actually will say that some of the
 14 findings here around no disruption of flow would
 15 be contradicted by some of the observations
 16 actually made in similar simulation studies.
 17 BY MR. GORDON:
 18 Q Tell me what --
 19 Well, first of all, in what way is -- is
 20 Dr. Al Garbashi's CFD more elegant than the one from
 21 Dr. Memarzadeh of the National Institutes of Health?
 22 A Well, I -- you know, I think a comparison
 23 will show --
 24 And, again, this is outside of my -- CFD
 25 modeling is specifically not something that I would

Page 177

1 place within my sphere of expertise.
 2 But there's a much higher level of
 3 documentation and intensity to try and develop
 4 components and models that simulate operating room
 5 conditions.
 6 Q What -- can you give me any examples of those
 7 elements that are present in Al Garbashi that are not
 8 present in the computational fluid dynamics model done
 9 by Dr. Memarzadeh?
 10 A I think that even a superficial look at
 11 Al Garbashi's paper compared to this one will show far
 12 greater effort to develop the -- the equations that
 13 describe what is going on in the -- in the operating
 14 room there that are -- and that are simulated.
 15 I mean, it's a very lengthy compilation
 16 and -- well, I have some ability to look at some
 17 of it. It's far more intense and deeply developed
 18 than this paper is.
 19 Q And -- and you thought the difference in
 20 elegance in the things you described between
 21 Al Garbashi and Dr. Memarzadeh was -- was so stark,
 22 that it wasn't even worth a note in your footnote or
 23 some comment in the text of your discussion of
 24 Memarzadeh -- or Al Garbashi's CFD that, "Oh, by the
 25 way, there's an independent CFD done by the National

Page 178

1 Institutes of Health that comes to a completely
 2 opposite conclusion"; right?
 3 MS. CONLIN: Objection as to form,
 4 argumentative.
 5 THE WITNESS: And I, frankly, would leave
 6 the computational fluid dynamic modelers to make
 7 their judgment. I gave you my view of why I
 8 looked at the Al Garbashi paper.
 9 BY MR. GORDON:
 10 Q Well, okay, we'll -- we'll -- fair enough.
 11 When you were writing your report, did you
 12 view your role as one of trying to analyze the
 13 totality of -- of relevant evidence and apply your
 14 best judgment while at the same time noting the areas
 15 where there was potential reasons to question or
 16 temper the conclusions that you reached?
 17 A I'm not sure I know what you mean.
 18 Q Do you think your -- did you view your
 19 role --
 20 In writing this report at the behest of
 21 plaintiff's counsel, were you -- were you an objective
 22 science -- scientist trying to address facts, good,
 23 bad, or indifferent, or were you trying -- or did you
 24 view your role as advocating for the plaintiff's
 25 position?

Page 180

1 Q Now, let's go back to -- well, I want to go
 2 back. You -- you said that -- words to the effect
 3 that -- I don't want to put words in your mouth -- but
 4 that the -- Al Garbashi's CFD was consistent with or
 5 confirmed by disruption studies. Again, whatever
 6 words you used.
 7 But I want to talk about what -- what studies
 8 you're talking about that you believe demonstrates the
 9 correctness of the Al Garbashi CFD and why the
 10 National Institutes of Health's CFD is wrong.
 11 MS. CONLIN: Well, objection as to form,
 12 argumentative.
 13 THE WITNESS: Yeah.
 14 MS. CONLIN: I mean, you've already
 15 talked to Dr. Al Garbashi about this specific
 16 issue in this report. I'm not sure why you're
 17 dragging Dr. Samet through it.
 18 MR. GORDON: Dr. Samet discussed
 19 Dr. Al Garbashi's --
 20 MS. CONLIN: Yeah.
 21 MR. GORDON: -- report and described it
 22 as elegant. He said it formed part of the basis
 23 of his opinion.
 24 MS. CONLIN: Is there a question pending?
 25 MR. GORDON: Yeah.

Page 179

1 A I viewed my role as advocating.
 2 Q But you viewed your role just specifically
 3 with respect to the CFD model as you, who is not an
 4 expert in CFD, deciding which CFD model was more
 5 elegant or more accurate or however you want to
 6 describe it?
 7 A In depth.
 8 Q In depth. The one by the hired expert for
 9 the plaintiffs versus the one done by the National
 10 Institutes of Health.
 11 And your -- your conclusion about that
 12 was that the difference was so stark, that you didn't
 13 even have to, as an objective scientist, mention "Oh,
 14 by the way there's this completely diametrically
 15 opposed conclusion coming out of an independent CFD
 16 done by somebody who doesn't have a dog in the fight"?

17 MS. CONLIN: Objection as to form,
 18 argumentative.
 19 THE WITNESS: It is included in the list
 20 of materials.
 21 BY MR. GORDON:
 22 Q It is included.
 23 There's not -- but there's not a syllable
 24 about it in the text; right?
 25 A It's not mentioned in the text.

Page 181

1 MS. CONLIN: What is it?
 2 MR. GORDON: Do you want to read it back.
 3 (The record was read by the
 4 reporter as follows:
 5 "Q. Now, let's go back to --
 6 well, I want to go back. You --
 7 you said that -- words to the
 8 effect that -- I don't want to put
 9 words in your mouth -- but that
 10 the -- Al Garbashi's CFD was
 11 consistent with or confirmed by
 12 disruption studies. Again,
 13 whatever words you used.
 14 But I want to talk about
 15 what -- what studies you're talking
 16 about that you believe demonstrates
 17 the correctness of the Al Garbashi
 18 CFD and why the National Institutes
 19 of Health's CFD is wrong.
 20 "A. Yeah.")
 21 MR. GORDON: I'm very impressed, by the
 22 way.
 23 Q But the specific question was, What are the
 24 studies that you're talking about?
 25 A So, again, the studies are listed in my

<p style="text-align: center;">Page 182</p> <p>1 expert report related to -- I think Table 3 is the 2 relevant -- the relevant table. Those are the various 3 studies involving bubbles and parallel counts.</p> <p>4 Q So Table 3 on page 24 lists four studies; 5 right?</p> <p>6 A That's correct.</p> <p>7 Q Okay. And the first one is McGovern, which 8 is -- there were two components to the study. We've 9 been talking most of the day about the observational 10 study.</p> <p>11 A Yes.</p> <p>12 Q You were talking here about the neutral 13 buoyancy detergent bubbles. And then there are two 14 studies by Legg and one by Belani; right?</p> <p>15 A Correct.</p> <p>16 MR. GORDON: Start with Exhibit 14. 17 (The aforementioned document was 18 marked Exhibit 14 for 19 identification by the reporter.)</p> <p>20 BY MR. GORDON:</p> <p>21 Q Is this the Belani study to which you were 22 opining?</p> <p>23 A That's correct.</p> <p>24 Q Okay. And on the first page of this 25 disclosure area, who does it indicate supported this</p>	<p style="text-align: center;">Page 183</p> <p>1 study?</p> <p>2 A It is supported by Augustine Temperature 3 Management.</p> <p>4 Q What -- what was your --</p> <p>5 When you wrote your report, what was your 6 understanding of what Augustine Temperature Management 7 was?</p> <p>8 A I assumed it was Augustine's company.</p> <p>9 Q The makers of HotDog? Did you understand 10 that?</p> <p>11 A Yes.</p> <p>12 Q And you see for Mr. Albrecht --</p> <p>13 And if I'm reading this legend properly, it 14 discloses his affiliation as Bioinformatics and 15 National Marrow Donor Program, Minneapolis, Minnesota?</p> <p>16 A Apparently, yes.</p> <p>17 Q Okay.</p> <p>18 A It looks like.</p> <p>19 Q Did -- did you know when you read this paper 20 that when Mr. Albrecht did the work that resulted in 21 this paper, the experiments, and the actual grafting 22 publication, that he was an employee of Augustine?</p> <p>23 A Sorry. That's not what -- the Bioinformatics 24 and National Marrow Donor Program related to other 25 statements.</p>
<p style="text-align: center;">Page 184</p> <p>1 I see he reveals under his conflicts. He 2 said he received paid support. But assuming his 3 position was elsewhere, if I'm reading the arrows 4 correctly.</p> <p>5 Q You are. And at the time that this was 6 ultimately published, he was an employee of the bone 7 marrow program.</p> <p>8 But the -- but as you point out, under the 9 conflicts of interest statement, not just the funding 10 source that we talked about, it says that Albrecht 11 received paid support salary from Augustine 12 Temperature Management. So I want to --</p> <p>13 You -- you knew when you read this that -- 14 that an Augustine employee was involved in this; 15 right?</p> <p>16 A That was clear. And I knew a little bit 17 about Augustine's history.</p> <p>18 MR. GORDON: I'm going to show you 19 Exhibit 15.</p> <p>20 (The aforementioned document was 21 marked Exhibit 15 for 22 identification by the reporter.)</p> <p>23 MS. CONLIN: I guess he's taking this 24 back.</p> <p>25 Do you want this all handed back?</p>	<p style="text-align: center;">Page 185</p> <p>1 MR. GORDON: Did we do that? We'll 2 just -- we'll keep them just so the record is 3 clear.</p> <p>4 Q Exhibit 15 is actually the literature, 5 Number 2 on your materials considered list; right?</p> <p>6 A Yes.</p> <p>7 Q But it's not one of the studies that you 8 listed that you -- that appears on Figure 3 in your 9 report or Table 3 -- excuse me -- Table 3; is that 10 right?</p> <p>11 A Correct.</p> <p>12 MS. CONLIN: Yeah. You're on Legg 2012 13 and Legg 2013, I believe.</p> <p>14 MR. GORDON: Right.</p> <p>15 Q I just -- I want to clear up that the -- 16 the -- the -- Exhibit 15, the -- the Albrecht 2011 17 paper, you -- it was material you had available to 18 you.</p> <p>19 Did it in any way impact your -- your 20 opinions?</p> <p>21 A You think it was part of the general 22 background of papers addressing issues related to the 23 Bair Hugger device.</p> <p>24 Q Okay. Well, do you -- I -- I generally don't 25 recall that we discussed filtration. This paper is</p>

<p style="text-align: center;">Page 186</p> <p>1 about filtration.</p> <p>2 A Frankly, I don't either.</p> <p>3 Q Did -- did you --</p> <p>4 A But, I mean, I listed it in the materials. I 5 certainly read this paper. I don't recall 6 specifically citing that, but I would have to go 7 through the report.</p> <p>8 Q I didn't really mean to mark it. But since I 9 did, I just wanted to find out.</p> <p>10 Did -- do -- do -- does anything --</p> <p>11 Any issue of filtration of, you know, the 12 Bair Hugger unit, does that play any role in the 13 opinions that you've come to?</p> <p>14 A Well, you know, I guess potentially in 15 that -- you know, this paper -- and I can't remember 16 what other papers addressed the filtration issue -- 17 questioned the efficiency of the filters.</p> <p>18 MR. GORDON: Okay. I'll show you 19 Exhibit 16. I've got it right this time.</p> <p>20 (The aforementioned document was 21 marked Exhibit 16 for 22 identification by the reporter.)</p> <p>23 BY MR. GORDON:</p> <p>24 Q This is -- Exhibit 16, is that the Legg the 25 2015 paper that you included on your Table 3?</p>	<p style="text-align: center;">Page 187</p> <p>1 A Correct.</p> <p>2 Q And when you read this, were you aware of any 3 involvement in the underlying study that's reflected 4 in Exhibit 16 of anybody connected to Augustine?</p> <p>5 A Not that I recall, no.</p> <p>6 Q And as you sit here today, was it your 7 understanding that the -- Exhibit 16, the study 8 reflected in there, was conducted entirely independent 9 of anybody connected with Augustine?</p> <p>10 A Well, looking at the report, I will -- I will 11 say I don't know if there's a conflict of interest 12 statement on file for these authors. But in the -- 13 what I have in my hand, there's no mention.</p> <p>14 Q But beyond -- my -- my question was beyond 15 anything that might be in -- in the text or appear 16 in --</p> <p>17 A No.</p> <p>18 Q -- Exhibit 16.</p> <p>19 A It says (reading): 20 "No benefits in any form have 21 been received or will be received 22 from a commercial party related 23 directly or indirectly to the 24 subject of this article." 25 That's at the end of the text.</p>
<p style="text-align: center;">Page 188</p> <p>1 Q And it -- I just want to clear --</p> <p>2 You have no additional information beyond 3 that, and as you sit here today, as far as you know, 4 this study was conducted without any involvement of -- 5 with anybody connected to Augustine; right?</p> <p>6 A Well, again, based on what is here, there's 7 no mention of any connection to any commercial person, 8 commercial entity.</p> <p>9 Q And you're -- you're probably being precise, 10 but -- and so I guess I need -- I want to be equally 11 precise. I'm not asking what's mentioned here.</p> <p>12 Do you have any independent source of 13 information that would lead you to believe that there 14 was any involvement with anyone connected with 15 Augustine in Exhibit 16?</p> <p>16 A I have no other knowledge of this paper other 17 than what I have in my hand.</p> <p>18 MR. GORDON: Okay. Now I want to show 19 you Exhibit 17.</p> <p>20 (The aforementioned document was 21 marked Exhibit 17 for 22 identification by the reporter.)</p> <p>23 BY MR. GORDON:</p> <p>24 Q This is a -- I hope I did it right -- the 25 Legg 2013 paper that you referenced in your table; is</p>	<p style="text-align: center;">Page 189</p> <p>1 that right?</p> <p>2 A Correct.</p> <p>3 Q And in Exhibit 17, there's no indication of 4 anyone or anything connected to Augustine had anything 5 whatsoever to do with the study reflected in 6 Exhibit 17; right?</p> <p>7 A There's a similar disclaimer at the end of 8 the -- at the end of the written text.</p> <p>9 Q And my question is the same as it was for 10 Exhibit 16.</p> <p>11 Do you have any independent knowledge from 12 any source beyond what is set out in the paper itself 13 that would indicate that this was any connection 14 between anybody connected to Augustine and the -- and 15 the study that is reflected in Exhibit 17?</p> <p>16 A The same answer. What I know about the paper 17 is what I'm holding in my hand.</p> <p>18 MR. GORDON: So now I'd like to show you 19 Exhibit 18.</p> <p>20 (The aforementioned document was 21 marked Exhibit 18 for 22 identification by the reporter.)</p> <p>23 BY MR. GORDON:</p> <p>24 Q This was previously marked as Albrecht 25 Exhibit 32.</p>

<p style="text-align: center;">Page 190</p> <p>1 But Albrecht was one of the ones where you 2 didn't have any exhibits provided to you; right? 3 A It's the one where I didn't list any of the 4 exhibits. 5 Q Yeah. So let me start by asking you if you 6 seen this before. 7 A I'm not sure. 8 Q Okay. I'll also direct your -- 9 A I think it's on my list of materials 10 considered. 11 Q Oh, okay. 12 A Yeah. 13 Q Did you say yes? 14 A No, it's not there. 15 Q Oh, okay. Well, the first page, as you can 16 see, is an email from Mark Albrecht at Augustine 17 Biomedical to Dr. Andrew Legg, Scott Augustine, 18 Christopher Nachtsheim. And the text says (reading): 19 "Hi, guys. I think the 20 manuscript is ready for first 21 review. Please let me know what 22 comments you may have. Thanks in 23 advance." 24 And if you turn to the second page, 25 there's a title page of something called </p>	<p style="text-align: center;">Page 191</p> <p>1 "Forced-air warming effective but risky. Patient 2 warming systems and their effect on orthopedic 3 Laminar ventilation." The authors listed are 4 Andrew Legg, Andy Hamer, Mark Albrecht, and 5 Christopher Nachtsheim. 6 Is this -- and my question now is, Is 7 this the first that you've seen a draft of a paper 8 with Legg, Hamer, and Albrecht as co-authors? 9 A I don't think I've seen this, yeah. 10 Q And I take it you have no knowledge that the 11 activities that are reflected in Exhibit 17, the Legg, 12 Hamer 2013 paper, the actual experiments that form the 13 basis for it were conducted by Mark Albrecht and 14 employees of Augustine Biomedical in conjunction with 15 Andy -- and Dr. Andrew Legg? 16 MS. CONLIN: Hold on. 17 Are you representing that Exhibit 18 is 18 the study reflected in Exhibit 17? 19 MR. GORDON: Yes, ma'am. 20 MS. CONLIN: I'm going to object. It 21 assumes facts not in evidence. 22 BY MR. GORDON: 23 Q So have you -- I -- I -- the -- my question 24 is -- I'm correct you haven't -- the -- my -- my 25 telling you -- and counsel has evidence that shows </p>
<p style="text-align: center;">Page 192</p> <p>1 otherwise she -- she knows how to handle that. 2 But I'm telling you the evidence -- sworn 3 testimony in -- in the record demonstrates that it was 4 Mark Albrecht and Andrew Legg together who did the 5 experiment that is described in Exhibit 17 and 6 discussed in a draft created by Mark Albrecht in 7 Exhibit 18. 8 You had no knowledge of that; correct? 9 A No. If -- if, in fact, these correspond, 10 which I haven't had a chance to -- 11 Q Yeah. 12 A -- make that judgment. 13 Q Would it matter? Not -- not the 14 correspondence. But would it matter to you if 15 Augustine personnel were involved in -- in both of the 16 Legg studies that you cited? 17 A The -- my first answer is I don't -- I don't 18 know whether it would matter if it raises the sort of 19 potential conflict of interest concern. But that's 20 all I can say. 21 Q Now, the four studies that you cite on 22 Exhibit 24 -- or Table 4. Excuse me. Table 3, on 23 Exhibit 1, page 24. 24 The McGovern paper, of course Mr. Albrecht of 25 Augustine Biomedical was one of them involved in that; </p>	<p style="text-align: center;">Page 193</p> <p>1 right? 2 A Correct. 3 Q And you know that Albrecht was involved, and 4 Belani is one of the co-authors; right? 5 A Correct. 6 Q And prior to today, you had no knowledge of 7 any involvement of Mr. Albrecht or anyone from 8 Augustine Biomedical in any of the Legg studies? 9 I represented to you that the August -- 10 Augustine personnel were involved in the 2012 study 11 based on his sworn testimony. And Mr. Albrecht and 12 Dr. Legg together conducted the experiments reflected 13 in Legg 2013. 14 A Yes. 15 Q If -- if my representation to you is -- is 16 accurate, the record is -- is correct, does it concern 17 you that all four studies that you're relying on as 18 demonstrating there's a potential for surgical site 19 contamination were conducted in some way with -- in 20 connection to Dr. Augustine's company that was making 21 a competing product? 22 MS. CONLIN: An objection as to form, it 23 assumes facts not in evidence with respect to all 24 these authors. 25 THE WITNESS: Sorry. Can you repeat it. </p>

Page 194

1 BY MR. GORDON:

2 Q I'll let her read it back.

3 A Okay.

4 Q You know what, no, I'll -- I'll rephrase it
5 and make easier and less convoluted.6 For purposes of my question, I would like you
7 to assume that Augustine personnel were involved in
8 the Legg 2012 study; that Mark Albrecht and Andrew --
9 and Andrew Legg together conducted the experiments
10 that resulted in Legg 2013 paper; and Albrecht, an
11 employee of Augustine, was involved both in McGovern
12 and Belani.13 If my representations are accurate, in other
14 words, all four studies have connections to Augustine,
15 does that give you any question or cause for concern
16 about relying on these four studies as indicators of
17 potential surgical site contamination with the Bair
18 Hugger?19 MS. CONLIN: The same -- the same
20 objection.21 THE WITNESS: I -- so at this point, I'm
22 going to have to say that, you know, the
23 postulated role for Albrecht in the other studies,
24 I just have no any knowledge.

25 ///

Page 195

1 BY MR. GORDON:

2 Q I -- I understand.

3 A So I'm trying to preface my answer by --

4 Q I understand --

5 A -- saying that.

6 And -- and, secondly, at least if I
7 understand, Albrecht -- what Albrecht has done is
8 research. I thought it was largely as an analyst,
9 which would not be surprising to find his name on
10 multiple publications.11 I guess it's another point if -- if the --
12 oh, gosh.

13 MS. CONLIN: This?

14 THE WITNESS: Exhibit 18 is, in fact,
15 the -- a precursor to Exhibit 17. The
16 decision-making around the authors would be of --
17 of interest, possibly of -- of concern.18 I think the only other comment I'll make
19 generically is that if you look at any papers
20 related to products, whether it's on -- whether on
21 pharmaceuticals or devices, the companies very
22 often fund research, and sometimes they fund
23 research directed at competitors. So that -- that
24 is -- the circumstance here is not a unique one.
25 ///

Page 196

1 BY MR. GORDON:

2 Q In your experience, is it typical for
3 companies to fund research directed against
4 competitors that are not disclosed in the -- in the --

5 MS. CONLIN: Objection --

6 Q -- publications?

7 MS. CONLIN: -- it calls for speculation,
8 and it assumes facts not in evidence.9 THE WITNESS: I -- I mean, I think the
10 only comment I can make is that I think
11 increasingly journals are very careful to get
12 disclosures.

13 BY MR. GORDON:

14 Q So you think that would be unusual or rare?

15 A By current standards, practice.

16 Q And current in this context goes back how
17 far? Five years? Ten years? Twenty years?18 A I would say it's been increasing strategic --
19 it probably started some decades ago.20 Q Well, back in 2012, 2013, would that be part
21 of the current era in your view?22 A I think certainly a disclosure was looked at.
23 It was undoubtedly requested.24 MR. GORDON: I'll show you Exhibit 19.
25 This was -- this was previously marked as Albrecht

Page 197

1 Exhibit 31.

2 (The aforementioned document was
3 marked Exhibit 19 for
4 identification by the reporter.)

5 BY MR. GORDON:

6 Q My first question is, Have you seen this
7 before today?

8 A You asked if I've seen it before?

9 Q Yes.

10 A I don't think so.

11 Q Okay. And the first thing I want to draw
12 your attention to the title of this email, which is
13 "publication factory continues."14 Have you ever described the research and
15 publishing work that you've done as a publication
16 factory?

17 A I don't think so.

18 Q Have you ever known anyone to do that,
19 describe the scientific -- scientific research that
20 they're conducting as being something from a
21 publication factory?22 A I'm not sure. Certainly people talk about
23 some labs that pour out the papers, but whether the
24 term "factory" idea used or not --

25 Q Okay. Let's look at the -- the -- who

<p style="text-align: center;">Page 198</p> <p>1 it's -- who this from and who it's to. The date is 2 July 9, 2010. It's from Mark Albrecht at Augustine 3 Biomedical to Mike Reed, Dr. Reed at Northumbria, 4 Dr. Paul McGovern. And the cc goes to 5 Scott Augustine, Augustine Biomedical; Andrea Lydel 6 [phonetic], Augustine Biomedical; Keith Leland at 7 Augustine Biomedical; R. Humboldt [phonetic] at 8 Augustine Biomedical; and Christopher Nachtsheim. You 9 received it, so...</p> <p>10 Do you see that?</p> <p>11 A Yes, I do.</p> <p>12 Q And then if you read the text, it says 13 (reading):</p> <p>14 "Paul and Mike, at this point 15 we have three completed manuscripts 16 that are ready to be submitted for 17 publication that you are both 18 authors on."</p> <p>19 And he describes them. And he says 20 (reading):</p> <p>21 "I've already sent you both 22 articles 1 and 2" -- "both of the 23 articles, 1 and 2. Article 3 is a 24 new one and arguably the best of 25 the three.</p>	<p style="text-align: center;">Page 199</p> <p>1 "When I'm in the U.K. next 2 week, I would like to plan a time 3 for us to get together, agree on 4 reviews, and submit these articles 5 at appropriate times."</p> <p>6 I -- I know this is the first time you've 7 seen this.</p> <p>8 But does this give you any cause for any 9 kind of concern that the published literature out 10 there on which you're relying was -- was being 11 written by Augustine's employee and submitted to 12 authors and with carbon copies to Augustine and 13 several other Augustine Biomedical employees?</p> <p>14 A Well, I -- what I don't know is the --</p> <p>15 MS. CONLIN: Are you representing these 16 are all the same studies that Dr. Samet has 17 submitted in his report? Because I don't think 2 18 and 3 are. So I just want to make sure.</p> <p>19 MR. GORDON: It's not his title. The 20 title's changed. And I don't think Number 2 was 21 ever published.</p> <p>22 THE WITNESS: This is --</p> <p>23 MS. CONLIN: I'm going to object to the 24 premise of your question.</p> <p>25 ///</p>
<p style="text-align: center;">Page 200</p> <p>1 BY MR. GORDON:</p> <p>2 Q Well, Dr. Samet, if -- if the evidence shows 3 in the sworn testimony of Dr. Reed, Dr. McGovern, 4 Dr. Legg, and Mr. Albrecht that Albrecht was involved 5 in all of the published studies, that Augustine was 6 being copied on drafts and involved in this, these 7 were being -- these were coming out of Augustine 8 Biomedical with carbon copies going to Scott Augustine 9 and everyone else, does that give you any cause for 10 concern about the validity or the integrity of these 11 studies?</p> <p>12 MS. CONLIN: And, again, I'm going to 13 object to the premise of the question as 14 misstating the record.</p> <p>15 THE WITNESS: But I think McGovern, Reed, 16 in particular as authors, have responsibility as 17 authors. And I don't know their role.</p> <p>18 My reading of these papers is the work 19 was done, I think, in all the cases in the U.K. 20 So presumably they were there.</p> <p>21 All authors have responsibility for the 22 data quality and the integrity of the 23 representation of the findings in the manuscript.</p> <p>24 So I -- there are more parties here, and 25 I can't speculate further based on what you have</p>	<p style="text-align: center;">Page 201</p> <p>1 said. I understand that Albrecht is here at this 2 point working for Augustine when this email was 3 sent.</p> <p>4 Q Dr. Samet, do you believe today that mumps 5 and measles and rubella vaccines causes autism?</p> <p>6 A I've been thinking why you're asking me the 7 question. The answer is no.</p> <p>8 Q The answer is no?</p> <p>9 A Do I think it causes autism?</p> <p>10 Q Yes.</p> <p>11 A No.</p> <p>12 Q Okay. In fact, pretty much the consensus in 13 the entire medical community is that MMR vaccines do 14 not cause autism; correct?</p> <p>15 A Yes.</p> <p>16 Q But there was a period of time when a 17 publication came out written and published in The 18 Lancet and authored by several U.K. doctors' 19 observational study that drew the conclusion that MMR 20 caused autism; correct?</p> <p>21 A It's a little bit more complicated if you're 22 referring to the original The Lancet paper by 23 Wakefield and others.</p> <p>24 Q I am.</p> <p>25 You're familiar with it?</p>

Page 202

1 A Correct.
 2 Q That had a pretty big impact on vaccination
 3 rates worldwide, didn't it?
 4 A In some places, it had an impact.
 5 Q And even today, it continues to have an
 6 impact on --
 7 A Unfortunately.
 8 Q And from your familiarity, I assume you --
 9 you know that at the time the publication was -- came
 10 out in The Lancet, Dr. Wake -- Dr. Wakefield, A, had a
 11 consulting agreement with plaintiff's lawyers who were
 12 trying -- who were preparing to bring lawsuits against
 13 the vaccine maker -- makers; and, B, had obtained
 14 patents on technology that he contended was a safer
 15 way of vaccinating for MMR that eliminated the risk of
 16 autism.
 17 Doctor, were you familiar with those?
 18 MS. CONLIN: I'm going to object --
 19 THE WITNESS: I'm familiar with
 20 Wakefield.
 21 MS. CONLIN: I'm going to object on
 22 relevance.
 23 You can answer.
 24 BY MR. GORDON:
 25 Q And -- and you're -- you know that all his

Page 203

1 co-authors were unaware of that connection.
 2 Do you know that?
 3 A As I said, I'm fully aware of the
 4 Wakefield --
 5 Q Well, I mean, is -- is that consistent with
 6 what you understand?
 7 A The paper was retracted -- retracted and the
 8 authors disavowed.
 9 Q Now, that paper had gone through peer review,
 10 hadn't it?
 11 A That's peer reviewed publication.
 12 Q Lancet is one of the probably top three
 13 medical journals in the world; right?
 14 A It's an important journal.
 15 Q Okay. That paper went through peer review.
 16 Wakefield's authors -- co-authors didn't know that he
 17 was -- had a lucrative consulting contract with
 18 plaintiff's lawyers and patents for -- for a
 19 potentially competing product for MMR, and they didn't
 20 know that he cooked the data, did they?
 21 A I think they were not aware of what he had
 22 done with the data.
 23 Q And neither were the reviewer -- the peer
 24 reviewers of Lancet; right?
 25 A No.

Page 204

1 Q And Lancet didn't withdraw the article for
 2 several years until an investigative journalist in
 3 England uncovered all the connections between
 4 Wakefield and the plaintiff's lawyers and his patents
 5 and demonstrated that he had fabricated data.
 6 Is that part of story as you understand it?
 7 A I've read those articles.
 8 Q Do you have any reason to think that The
 9 Lancet independently pulled its -- pulled that article
 10 or withdrew it, having nothing to do with the work of
 11 that -- the investigative journalists?
 12 A Questions were raised about that report for a
 13 long -- a long time. And what tipped Lancet over,
 14 perhaps it was those papers. But I think eventually
 15 the literature were then clarified.
 16 Q Peer reviewers can only review what's
 17 submitted to them?
 18 A By definition.
 19 Q They -- unless the -- an author submits raw
 20 data, peer reviewers have to take the representations
 21 of -- and they even submitted -- a paper submitted for
 22 publication regarding the data and the data analyses
 23 as -- as having been accurately, with integrity, with
 24 honesty, and with objectivity; right?
 25 A And they would look for indications of

Page 205

1 deviations from standard practices or a lack of -- a
 2 lack of validity. Sometimes such things are
 3 identified at the peer review process.
 4 Q Well, and in the case of the Wakefield, et
 5 al., paper, nobody caught any of those issues for
 6 quite a while after -- after publication, right,
 7 including the peer reviewers?
 8 A Correct.
 9 Q You would agree that peer review in and of
 10 itself is not a magic wand that guarantees that
 11 whatever is coming out of even the most prestigious
 12 journalist is objective, accurate, no errors, no
 13 hidden agendas; right?
 14 A Well, a peer review is a -- a -- one of the
 15 points of checks on what is in manuscript and the
 16 appropriateness of the analysis findings and maybe
 17 looks at the data and how the authors are published.
 18 It's a multi -- multifaceted process. Then, of
 19 course, the journals themselves, the publications.
 20 MR. GORDON: Could we take a quick break.
 21 MS. CONLIN: Sure.
 22 MR. GORDON: I'm segueing to a related
 23 but slightly different discussion now.
 24 THE VIDEOGRAPHER: The time is 4:35 p.m.
 25 We are off the record.

Page 206

1 (A brief recess was taken.)

2 MS. CONLIN: I've been informed that
3 there's about two and a half hours left.

4 Dr. Samet announced his departure from
5 the USC today, which is -- caused a number of
6 disruptions to his schedule for today.

7 Granted has afforded the courtesy of
8 regrouping at a different point in time, because I
9 will have a drive. There's some things that need
10 to be explained and updates based on the
11 examination today and the way things are
12 characterized.

13 But we will endeavor to get a date that
14 works for Dr. Samet in sufficient time in advance
15 of the August 16 deadline.

16 And I don't know if you have anything to
17 add, Mr. Gordon.

18 MR. GORDON: No.

19 MS. CONLIN: Okay. That's it.

20 MR. GORDON: Other than -- I agree.

21 (The deposition proceedings were
22 adjourned at 4:44 p.m.)

23 -000-

24

25

Page 207

1 STATE OF CALIFORNIA)

2) ss.

3 COUNTY OF LOS ANGELES)

4 I, JONATHAN SAMET, M.D., having appeared for my
5 deposition on July 11, 2017, do this date state that I
6 have read the foregoing deposition and that I have
7 made any corrections, additions, or deletions that I
8 was desirous of making in order to render the within
9 transcript true and correct.

10 IN WITNESS WHEREOF, I have hereunto subscribed my
11 name this day of , 2017.

12 _____
13 JONATHAN SAMET, M.D.

14

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Page 208

1 DEPONENT'S CHANGES OR CORRECTIONS

2 Note: If you are adding to your testimony, print the
3 exact words you want to add. If you are deleting from
4 your testimony, print the exact words you want to
5 delete. Specify with "add" or "delete" and sign this
6 form.

7 DEPOSITION OF: JONATHAN SAMET, M.D.

8 CASE: IN RE BAIR HUGGER FORCED AIR
9 WARMING PRODUCTS LIABILITY

10 LITIGATION

11 DATE OF DEPOSITION: JULY 11, 2017

12

13 PAGE LINE CHANGE/ADD/DELETE

14

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Deponent's Signature Date _____

Page 209

1 PAGE LINE CHANGE/ADD/DELETE

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Deponent's Signature Date _____

Page 210

1 CERTIFICATE OF REPORTER

2 I, DORIEN SAITO, CSR 12568, CLR, a certified
3 Shorthand reporter in and for the State of
4 California, County of Los Angeles, do hereby certify;

5 That JONATHAN SAMET, M.D., the witness named
6 in the foregoing deposition, was, before the
7 commencement of the deposition, duly administered an
8 oath in accordance with CCP 2094;

9 That said deposition was taken down in
10 stenograph writing by me and thereafter transcribed
11 Into typewriting under my direction.

12 That before completion of the deposition,
13 review of the transcript [] was [] was not
14 requested. If requested any changes made by the
15 deponent (and provided to the reporter) during the
16 period allowed are appended hereto.

17 I further certify that I am neither counsel
18 for nor related to any party to said action, nor in
19 any way interested in the outcome thereof.

20 Dated this 14th day of July, 2017.

21
22 CERTIFIED SHORTHAND REPORTER
23 IN AND FOR THE COUNTY OF
24 LOS ANGELES, STATE OF CALIFORNIA
25

A	191:11	affiliation (1)	208:9	76:3,5,25 83:4
A.J (4)	25:5 33:22 41:8 62:22	183:14	air-handling (2)	92:12,16 93:25
6:14,14,17,17	64:14 104:12	afforded (1)	27:6,9	94:18 103:22
a.m (3)	111:12 121:12	206:7	airborne (10)	107:10 113:4 116:1
2:14 7:2,14	183:21 191:12	aforementioned (19)	6:9 13:6,10 22:19	125:24 138:6 139:3
ability (1)	add (5)	28:22 61:7 71:7 84:20	23:2,22 24:1 25:10	139:8 140:22
177:16	128:8 129:14	128:11 136:14	26:23 27:3	149:24 164:9
able (1)	132:11 141:20	airflow (3)	169:13 176:9	169:13 176:9
118:9	137:13 141:20	6:14,17 61:16	205:16	
absence (2)	142:16 149:14	al (28)	analyst (2)	
86:20 93:4	169:20 182:17	5:7 40:12 42:17 55:17	66:12 195:8	
absent (1)	184:20 186:20	65:16 69:19 169:14	analyze (3)	
167:4	188:20 189:20	172:5 173:19,20	116:14 162:8 178:12	
absolute (1)	197:2	176:4,5,6,7,10,20	analyzed (1)	
38:14	AFTERNOON (1)	177:7,11,21,24	45:11	
absolutely (7)	4:5	178:8 180:4,9,15,19	ancillary (1)	
45:1,13 46:20,24 47:4	Agency (2)	181:10,17 205:5	87:4	
47:9 57:9	143:23 145:25	Albrecht (56)	and/or (5)	
abstract (1)	agendas (1)	5:6,8,16 6:6,10,18,21	65:12 68:10,14 69:2	
64:10	205:13	40:11 44:1,3 61:6	91:4	
acceptable (5)	agent (7)	66:3,11 74:7,8,14	Andrea (1)	
25:13,19 26:1,15,20	37:11,16 54:6,6,24	76:7,17,22 94:5	198:5	
acceptance (4)	55:5,18	129:7 130:13,21	Andrew (7)	
30:19 31:6 111:13	agents (14)	132:21 133:2	6:19 190:17 191:4,15	
112:7	17:3,6 21:5,7,12,14	137:12 138:1,2	192:4 194:8,9	
accepted (3)	21:16 22:4,6,11,14	139:12 149:22	Andy (2)	
111:22 112:1,2	22:20 23:2 55:12	183:12,20 184:10	191:4,15	
account (1)	aggregate (2)	185:16 189:24	anesthesia (2)	
126:22	113:4 120:2	190:1,16 191:4,8,13	12:25 13:17	
accounts (1)	ago (8)	192:4,6,24 193:3,7	anesthesiologist (1)	
109:6	8:22 13:20,21 32:12	193:11 194:8,10,23	13:23	
accurate (15)	34:8 71:18 74:16	195:7,7 196:25	anesthesiology (2)	
33:13 91:6 104:6,7	196:19	198:2 200:4,4 201:1	13:24 14:1	
105:22 126:13,13	agree (27)	Albrecht's (7)	Angeles (8)	
131:16 148:15	36:24 62:8 74:21 82:8	41:20 73:19 76:15	1:14 2:13 7:1,13 97:1	
156:25 162:18	85:25 86:14 87:8	129:5 130:9 136:21	207:2 210:4,23	
179:5 193:16	90:24 91:10 93:8	151:13	animal (1)	
194:13 205:12	101:21 102:9	algebra (1)	80:6	
accurately (2)	109:13 114:19	52:25	announced (1)	
127:7 204:23	115:10 119:1	Alizant (1)	206:4	
achievable (1)	153:20 156:20	7:22	annual (1)	
26:4	157:24 158:22	allow (2)	156:17	
achieve (3)	172:6 173:8,23	47:7 126:21	answer (19)	
25:13 50:5,8	175:4 199:3 205:9	allowed (2)	4:11 56:4 76:22 82:18	
achieved (2)	206:20	79:1 210:16	84:11 100:1 105:12	
26:21 107:17	agreed (2)	allows (1)	110:15 111:8	
action (3)	12:1 76:17	64:11	114:18 155:15	
145:6 146:7 210:18	agreement (1)	amount (3)	159:21 167:9	
active (7)	202:11	19:4 121:18 156:23	189:16 192:17	
104:10,19,21 105:3	ahead (1)	analogy (1)	195:3 201:7,8	
107:14 141:15	121:10	120:4	202:23	
155:19	air (20)	analyses (4)	answered (5)	
activities (10)	1:4 2:4 6:13 7:8 19:13	93:3 121:12 164:7	23:7 100:13 125:11	
17:11 20:21 22:19	19:14,17,20,22 20:1	204:22	148:6 154:22	
24:6 26:25 27:14	20:3,6 21:14 25:10	analysis (26)	answering (1)	
28:1 36:8 37:2	25:13,19 26:1,15,20	66:18 75:12,21,22	103:12	

anti (1) 68:10	10:10 140:21	asked (7) 9:25 10:11 23:7 28:9 111:14 154:22 197:8	184:2	authored (3) 32:2 36:21 201:18
antibiotic (11) 49:5 68:20 69:2,7 70:5 77:14 97:17 98:6,9 100:3 115:11	approaches (2) 14:20 35:19	assumption (1) 127:7	authority (1) 70:22	
antibiotics (19) 49:9 65:12 68:10,15 69:21 74:18,23 75:3 76:11,18 93:12 94:1 94:8,20 97:15 112:19,24 114:1,21	appropriate (3) 110:17 139:2 199:5	assurance (1) 146:5	authors (14) 55:17 85:7 187:12 191:3 193:24 195:16 198:18 199:12 200:16,17 200:21 203:8,16 205:17	
anticipated (1) 30:2	appropriateness (1) 205:16	asthma (2) 16:20 17:13	autism (5) 201:5,9,14,20 202:16	
Antonio (1) 10:21	approximately (3) 7:14 134:5 144:23	attempts (1) 91:4	available (9) 41:6 49:19 64:22 75:8 113:12 128:12 129:9 170:19 185:17	
anybody (5) 167:4 187:4,9 188:5 189:14	April (1) 161:15	attendance (1) 145:7	average (25) 86:9,22 111:9 123:7 128:19 129:25 130:1,4 131:20 158:16 159:23 160:8,15,16,20 161:5,7,13,16,24 162:6,10 163:23 164:11,17	
apnea (2) 16:25 17:1	area (7) 17:16 18:1,5 31:11 149:9 154:8 182:25	attention (4) 125:1 136:20 149:21 197:12	averaged (1) 160:2	
apologize (4) 32:18 52:25 154:21 155:13	areas (4) 13:15 14:25 18:10 178:14	attest (1) 110:19	averaging (1) 164:2	
apparent (1) 88:2	arena (2) 9:19 11:20	attributable (18) 36:6 38:1,6,15,20,24 38:25 39:8,13,20,22 41:1 61:20 99:13,20 107:1 108:9 158:17	aware (32) 53:18 66:17,19,20,22 69:18 70:1,3 108:25 109:3,5,9,11,19,21 110:12 120:14 124:17,18,21,22,23 125:7 152:3,12,16 152:21 153:4,18 187:2 203:3,21	
Apparently (1) 183:16	arguably (1) 198:24	attributed (1) 41:19	B	
appear (3) 29:10 137:17 187:15	argument (1) 65:9	audible (2) 171:18 172:19	B (7) 4:14 5:2 6:2 17:7,20 17:21 202:13	
appeared (2) 34:14 207:4	argumentative (3) 178:4 179:18 180:12	August (4) 136:4 139:14 193:9 206:15	back (38) 9:20 10:20 24:19 41:21 48:20 49:12 60:23 74:11 76:1	
appears (8) 36:20 87:16 129:19 134:22 142:12 146:20 170:17 185:8	arises (1) 48:16	Augustine (54) 5:7,9 6:19 30:8 32:7 32:20 33:10,21 34:3 34:6,17,20 66:21 67:1,23 71:22 72:5 109:2 111:25 132:22 165:22 183:2,6,22 184:11 184:14 187:4,9 188:5,15 189:4,14 190:16,17 191:14 192:15,25 193:8,10 194:7,11,14 198:2,5 198:5,6,7,8 199:12 199:13 200:5,7,8 201:2	82:23 97:11 98:14 111:10,22 112:19 134:7 135:5 139:4 139:15,17 140:11 141:9 147:3 151:19 151:25 157:2 160:9 161:14 180:1,2	
 appended (1) 210:16	arithmetic (2) 39:5,10	association (26) 7:19 36:3 50:19,22 52:3 62:4,16,19,24 63:1,6,10,12 64:3		
applicable (1) 40:4	Arthroplasty (4) 4:18 5:4 6:12,15	64:12,22,24 65:15 78:22 79:1 80:17 81:23 82:11 91:15 126:20,20		
application (3) 39:15 158:23 159:16	article (12) 4:18 5:4 6:4,8,12,15	associations (6) 62:10 80:21,23 82:24 83:18 91:9		
applied (1) 63:2	articles (8) 57:17,20 58:10,12	assume (9) 18:4 33:6 42:25 93:3 103:19 131:22		
apply (1) 178:13	asbestos (2) 198:22,23 199:4 204:7	170:12 194:7 202:8		
appointed (1) 146:20	ASHRAE (9) 10:22 11:4	assumed (1) 183:8		
appointment (1) 146:9	13:9 18:19,24 19:8	assumes (7) 75:21 94:10 109:16 117:5 191:21		
approach (9) 5:19 21:2 25:25 58:11 75:6 85:3 91:1 167:10 176:12	24:19 25:25 26:14	193:23 196:8		
approached (2)	26:18 27:1	assuming (4) 18:10 75:15 126:8		
	13:13 49:23 57:10	author (2) 110:22 204:19		
	65:11 68:9			

181:2,5,6 184:24,25 194:2 196:16,20 background (8) 12:24 16:3 19:15 27:6 27:13 34:17 44:6 185:22 bacteria (8) 15:12,14,15,17,21 20:18 98:7,10 bacterial (3) 20:13 113:13 120:7 bad (1) 178:23 Bair (74) 1:4 2:4 7:7 10:12 12:18 35:3,8,9 49:15 53:8,14 54:20 67:2,6,11,24 69:6 69:12,18,20,20 70:4 70:6 72:2 74:17,24 75:2,5 76:10 94:1 98:2 101:14,25 102:23 103:8,10 105:7 106:25 107:2 107:4,15 108:8,19 108:24 109:14 114:16 116:12 117:16 120:6,14,15 122:20 130:1 135:17 152:6,15 155:24 156:2 158:1 159:18,18 160:4 161:11 163:13,20 165:15 166:19 168:5,22 169:5 185:23 186:12 194:17 208:9 barely (4) 127:2 132:23 139:12 140:8 base (3) 100:21 101:4 103:18 based (49) 14:2 34:23 35:7 36:2 38:23 39:2 40:9 46:6 49:21,22 53:22 54:11 61:21,24 63:1 76:2 80:6 82:25 84:6 89:6 91:3 93:23 102:21 108:9 113:4 121:25 122:12 125:24 126:1 127:9,11,15 135:23 138:4 143:3 146:12,19 150:4 151:6 157:24 161:3	165:1,8 166:13 167:13 188:6 193:11 200:25 206:10 basic (1) 174:14 basis (11) 36:15 37:25 59:14 85:17 91:12 93:17 94:15 103:12 149:1 180:22 191:13 began (3) 141:15 142:21,25 beginning (6) 73:4,8,11,19,22 105:16 behalf (5) 2:11 7:21 8:1 71:13 173:13 behaviors (1) 87:25 behest (1) 178:20 Belani (9) 6:6,11 40:12 42:22 43:19 182:14,21 193:4 194:12 believe (16) 11:6 27:1 29:17 41:20 67:14 80:18 134:22 157:13 159:16 168:21 169:3 180:8 181:16 185:13 188:13 201:4 beneficial (1) 84:13 benefit (6) 54:2 87:21 88:3 89:14 90:14 159:6 benefits (2) 89:9 187:20 best (9) 74:24 127:17 159:24 160:6 164:10,16,19 178:14 198:24 better (5) 13:14 52:13,22 116:10 142:14 beyond (7) 58:4 154:17 173:22 187:14,14 188:2 189:12 bias (18) 47:13,16,18,23,25 48:3,7,15,16,16,21 48:23 49:2 50:1,17	51:23 52:11 91:25 biased (1) 93:1 biasing (1) 87:2 bid (1) 146:9 big (3) 89:7 106:12 202:2 bigger (2) 16:19 81:1 binary (1) 62:15 Bioinformatics (2) 183:14,23 Biomedical (12) 66:21 190:17 191:14 192:25 193:8 198:3 198:5,6,7,8 199:13 200:8 biostatistics (1) 70:23 Birmingham (1) 145:9 bit (5) 40:6 66:14 142:13 184:16 201:21 bits (2) 74:12,12 black (1) 21:6 BLACKWELL (1) 3:9 blank (1) 42:16 blanket (1) 101:25 blankets (3) 6:16 101:7,10 bleeding (1) 55:7 blowers (1) 6:8 Blumenthal (1) 88:5 board (3) 24:12,14,16 bodies (1) 164:25 body (1) 167:14 bone (1) 184:6 books (1) 11:25 Boone (2)	3:15 7:23 Borak (4) 3:15 7:24 44:7 72:23 Borak's (2) 72:8 147:20 bottom (4) 35:6 38:17 86:18 168:13 BR (1) 150:3 brain (2) 118:25 119:18 brand-new (1) 34:14 break (8) 60:1,13 94:23 95:2 149:7,10 151:21 205:20 breakdown (2) 113:9 114:9 brief (6) 8:21 60:22 112:16,16 151:24 206:1 briefer (1) 112:10 bring (1) 202:12 Britain (1) 156:12 broad (3) 19:15 20:8 77:25 broader (3) 18:3 89:11,23 broadly (4) 15:25 20:11 27:16,18 broke (1) 129:4 brought (6) 19:8,12,12,13 34:7 124:25 bubble (1) 141:4 bubbles (3) 61:16 182:3,13 bucket (2) 13:13 18:23 buckets (1) 13:12 buildings (6) 25:7 26:9,11,16,20 27:7 bunch (1) 158:19 bundle (3) 154:2,2 158:21 bundles (1)	154:14 buoyancy (1) 182:13 Buren (1) 42:17 BURKE (1) 3:9 <hr/> C (14) 3:1 29:5,17,21,22 33:1,2 41:25 42:6,8 57:21 58:18 73:1 74:4 calculate (1) 125:12 calculated (7) 39:20 77:22 104:6 123:5,17,25 135:15 calculation (7) 38:1 39:7,10,18 123:4 125:24 126:15 calculations (4) 126:4,6,13 127:16 California (8) 1:14 2:13 7:1,13 97:1 207:1 210:4,23 call (2) 13:12 39:23 called (6) 25:24 67:17,18 87:4 111:18 190:25 calls (7) 38:8 99:24 165:19 166:23 167:1 174:1 196:7 cancer (25) 16:15,18 17:3,6,8,13 79:19 80:4,15 81:19 81:24 105:15,17,23 106:3,13 118:24,25 119:3,6,11,12,18,21 119:24 cancers (5) 17:13 118:22 119:16 119:18 120:2 Cannon (1) 6:14 capable (1) 20:12 carbon (3) 21:6 199:12 200:8 cardiac (1) 17:13 cardioprotective (4) 87:24 88:14,24 89:19
---	--	--	---	--

cardiovascular (11) 16:24 87:16,21 88:10 89:9,15 90:5,15,16 90:21,23 care (7) 16:4,5 154:1,1,2,14 158:21 career (14) 9:21 10:20,22 14:8,10 15:8 17:8,17 23:1,3 23:6,11,12 110:20 careful (1) 196:11 carefully (3) 46:14 70:12 72:23 carried (1) 175:24 carries (1) 27:8 carry (1) 174:20 case (22) 4:24 7:10 10:10 11:1 11:4,18,19,25 12:9 40:3 46:18 47:15 53:25 77:13 80:14 106:9 115:9 162:5 169:15 170:17 205:4 208:9 cases (16) 9:8,14 108:3,12 109:6 114:6 115:6,8 117:12,25 118:4,6 118:18 119:11 150:18 200:19 categories (1) 63:13 categorized (1) 62:10 caught (1) 205:5 causal (11) 28:3 36:7,10 37:17 53:13 85:4,12 87:1 91:12 92:18,22 causation (5) 35:19,20 37:9,14,16 cause (25) 17:3 35:10,15,20 36:14,19 37:1,11,21 37:21 38:3,7,21,22 50:24 100:3 105:24 108:8 119:5,21 165:16 194:15 199:8 200:9 201:14 caused (5)	99:22 100:10 142:5 201:20 206:5 causes (6) 23:24 87:4 120:6 127:21 201:5,9 causing (5) 20:12 24:4 79:24 102:1,16 cc (4) 5:7,9,16 198:4 CCP (3) 8:14 97:7 210:8 CDC (1) 4:22 center (1) 24:11 century (2) 105:16,18 certain (2) 20:4 86:17 certainly (24) 12:10 14:3,18 15:4,9 16:13,21 20:2,7 22:2,13 37:15 56:18 56:23 78:9 85:25 87:8 98:21 111:15 115:13 126:6 186:5 196:22 197:22 CERTIFICATE (1) 210:1 certified (2) 210:2,22 certify (2) 210:4,17 CFD (15) 172:2 176:20,24 177:24,25 179:3,4,4 179:15 180:4,9,10 181:10,18,19 CFW (1) 151:3 chaired (3) 26:18,22 145:16 challenge (1) 73:13 challenges (1) 86:16 chance (1) 192:10 change (7) 50:1 114:1 115:11 152:16 153:9 158:18 165:1 CHANGE/ADD/D... 208:14 209:1 caused (5)	152:13 153:14 199:20 changes (7) 14:13 144:4 153:19 154:15 158:19 208:1 210:14 Chapter (1) 85:3 character (1) 48:1 characteristic (1) 87:14 characteristics (5) 87:24 88:14,24 89:19 89:22 characterize (9) 12:20,21 17:18 20:23 23:10 28:1 38:15 48:2 78:12 characterized (3) 21:19 92:14 206:12 characterizing (2) 41:16 143:4 chart (11) 134:21 135:3,12,14 135:23 142:11 156:8,20 160:10,17 163:2 chase (1) 138:13 check (2) 106:16,19 checked (1) 150:5 checks (1) 205:15 chi-square (2) 135:15,20 China (1) 24:9 chose (2) 58:6 175:20 Christmas (1) 112:7 Christopher (7) 5:16 6:6,19 132:22 190:18 191:5 198:8 cigarette (7) 19:5 79:18 80:4 81:18 105:15 106:14 119:2 cigarettes (1) 106:6 circumstance (1) 195:24 circumstances (3) 86:17 107:21 164:20	Ciresi (13) 3:3 8:1 10:11,14 11:13,23 12:3,7,10 43:5 58:24 59:3,18 cite (1) 192:21 cited (5) 70:20 102:21 168:25 169:25 192:16 citing (3) 88:5,12 186:6 civil (1) 173:13 claiming (1) 15:2 claims (2) 9:8,15 clarified (1) 204:15 clarify (7) 56:11 71:4,24 130:13 141:10 163:8,9 clarifying (1) 59:1 Class (1) 31:21 classification (1) 63:18 classify (1) 46:5 clear (13) 44:16 58:15 89:9 90:14 148:8 155:16 160:25 163:3 173:17 184:16 185:3,15 188:1 cleared (1) 172:10 clearer (1) 87:20 clearly (3) 77:6 138:22 160:25 clinical (13) 14:8,10 15:4,7 16:3 82:12 83:14,20 89:10 90:18 91:5 145:8,20 clinicians (1) 105:23 clipping (1) 150:18 clogs (1) 153:16 close (1) 18:9 closely (2)	12:14 23:17 CLR (3) 1:25 2:15 210:2 co-authored (3) 32:2 36:4,21 co-authors (5) 85:13 191:8 193:4 203:1,16 coherence (2) 106:20,23 coherent (1) 91:15 cohort (10) 69:21 80:13 89:11 97:23,25 99:3,3 114:7,12,17 coincident (1) 106:5 colleagues (1) 19:16 collection (1) 133:18 collective (1) 174:19 column (1) 143:19 combination (3) 68:20 97:24 155:18 combinations (1) 69:4 combine (1) 87:1 combined (1) 144:14 come (10) 10:8 30:18 32:8 46:10 58:23 59:16 75:7 91:23 175:17 186:13 comes (3) 98:22 124:2 178:1 comfort (1) 64:3 comfortable (1) 126:21 coming (9) 13:8 39:13 54:19 79:25 118:17 123:23 179:15 200:7 205:11 commencement (1) 210:7 commencing (1) 2:13 comment (22) 49:23 59:19 74:2
--	---	--	--	---

81:21 82:5 84:3 113:18 126:11,24 130:6 133:16,24 135:8 137:20 138:20 161:25 164:6 165:20 167:18 177:23 195:18 196:10 commented (4) 79:20 94:12 125:7 127:24 comments (4) 77:5 111:10 131:18 190:22 commercial (7) 25:7 26:9,11,16 187:22 188:7,8 committee (8) 13:9 18:20,21 19:1,8 24:19 25:23 26:18 common (6) 55:25 56:7 81:11 127:25 136:8 150:6 community (2) 84:8 201:13 companies (2) 195:21 196:3 company (6) 66:21 67:14,24 68:2 183:8 193:20 comparable (3) 103:20 104:13 119:3 comparatory (1) 67:21 compare (5) 75:2 94:6 103:24 162:10 176:9 compared (9) 50:24 76:10 99:2,21 101:14 118:21 119:14 163:23 177:11 compares (1) 101:18 comparing (5) 51:12 76:19 102:10 134:8 164:3 comparison (7) 35:4 77:7 100:20,22 101:5 107:11 176:22 competing (2) 193:21 203:19 competitors (2) 195:23 196:4 compilation (4)	43:6 44:13,15 177:15 compile (1) 41:12 compiled (1) 82:25 complete (2) 29:7 139:25 completed (3) 55:6 146:1 198:15 completely (3) 94:7 178:1 179:14 completion (1) 210:12 complex (1) 26:6 complicated (1) 201:21 Complies (1) 8:5 component (3) 61:22,25 141:3 components (5) 61:14,15,17 177:4 182:8 composite (1) 119:24 comprehensive (3) 19:20 33:1,6 comprises (1) 131:20 compromised (1) 121:15 computation (1) 39:5 computational (10) 169:1,10,13 171:20 172:2,14 175:23 176:12 177:8 178:6 computed (3) 121:18,19,19 con (1) 88:17 concept (3) 35:16 45:24 46:24 concern (7) 20:9 192:19 193:16 194:15 195:17 199:9 200:10 concerned (3) 25:1,2 74:15 concerns (2) 51:23 52:10 conclude (9) 150:23 173:10,11 184:1,9 confound (2) 50:13 87:12 confounded (2)	concluded (12) 26:6 35:7 44:25 46:19 47:15 48:22,25 56:15 63:24 108:7 113:25 114:4 concludes (1) 81:13 concluding (1) 81:13 conclusion (16) 46:10 47:8,11 54:15 56:13 91:24,24 106:4 159:18 165:7 166:14 167:13 178:2 179:11,15 201:19 conclusions (13) 36:7 61:19 80:4 83:11 91:12 101:23 114:3 164:15 165:7 166:6 166:21 171:2 178:16 condensation (1) 29:6 conditions (3) 17:14 36:11 177:5 conduct (1) 55:15 conducted (6) 187:8 188:4 191:13 193:12,19 194:9 conducting (1) 197:20 conductive (5) 30:11 49:15 101:10 116:12 118:14 conference (1) 145:8 confidence (12) 77:7,16,23 78:1,3,13 92:4 111:4 126:16 127:1,4 151:4 confining (1) 165:12 confirmed (2) 180:5 181:11 conflict (10) 171:24 172:7,12,23 173:2,14,15,24 187:11 192:19 conflicts (5) 150:23 173:10,11 184:1,9 confound (2) 50:13 87:12 confounded (2)	92:19 101:23 confounder (22) 49:13,25 50:3,9 51:22 52:10,15 53:4,13,21 53:24 64:8 74:24 75:1 81:8,15 92:1 92:13 114:22 115:12,15 116:7 confounders (18) 48:21,22 49:1,9,20 62:3 64:1,8 79:14 79:24 81:16 82:3 87:5 92:8 93:10,16 93:20 126:22 confounding (25) 48:6 49:3 52:17 64:5 64:16 65:10,14,19 68:11,22 77:14 78:24 79:2,10 81:25 82:2 87:13 88:13 89:19 92:22 93:4 114:4 116:3 118:10 153:9 confused (1) 52:5 conjunction (2) 64:13 191:14 Conlin (107) 3:3,4 7:25,25 8:1 10:11 11:23 12:4,10 23:7 32:11 37:4,6 38:8 42:6 43:5 45:3 45:6 51:9 58:24 59:3,18 60:5,9,12 60:15,19 81:20 94:10,22,24 95:4 99:24 100:25 101:8 102:4,18 109:16 114:24 117:5 121:9 125:18 128:22 129:4 131:2,7 133:15 134:13 138:18 139:20,22 140:5,9 142:7 143:7 143:9,11 146:16 147:4,10,11 148:16 148:18 149:6,8 153:2 158:3,24 160:23 162:13,20 162:22 163:1 165:4 165:19 166:23 167:1 170:3,10 173:4 174:1 176:4,6 178:3 179:17 180:11,14,20,24 181:1 184:23	185:12 191:16,20 193:22 194:19 195:13 196:5,7 199:15,23 200:12 202:18,21 205:21 206:2,19 connected (6) 187:4,9 188:5,14 189:4,14 connection (9) 10:15 16:11 27:1 130:22,23 188:7 189:13 193:20 203:1 connections (2) 194:14 204:3 conscientious (1) 112:13 consensus (4) 19:2 25:25 84:7 201:12 consequence (1) 88:18 consequences (4) 4:23 84:17 102:23 103:3 consider (17) 10:13 12:5 13:25 15:22 18:12,15,18 22:22 23:25 51:22 63:22 64:13 77:16 78:3 100:2 106:22 154:7 consideration (5) 65:17 66:2 110:1 152:10 165:14 considerations (2) 54:12,14 considered (20) 20:5 29:6,18,23 37:12 40:11 41:22 48:11 50:21 52:9 54:18 65:21 68:19 93:11 94:16 106:20 167:20 170:16 185:5 190:10 considering (2) 68:15,24 consistency (1) 91:19 consistent (5) 81:6 150:2 180:4 181:11 203:5 consistently (1) 107:16 constitute (1)
---	---	--	---	---

172:12	101:7	192:8 193:2,5,16	covered (2)	76:5 77:10 82:3,25
constitutes (2)	convenient (1)	201:14,20 202:1	covers (1)	84:6 89:7 100:21
37:20 62:25	60:16	205:8 207:9		101:4,13,16 109:22
consult (1)	conversations (1)	corrections (2)		112:17 113:5,18,24
28:9	9:23	207:7 208:1	101:11	115:16,21 118:16
consultant (2)	converse (1)	correctly (4)	create (1)	120:24 124:12
9:25 145:17	21:15	12:12 126:7 140:15	created (1)	125:5,6,7,25 128:19
consulting (2)	convey (1)	184:4	192:6	133:13,18 134:1
202:11 203:17	131:15	correctness (2)	criteria (4)	136:23 137:2,9,18
contact (1)	convicted (1)	180:9 181:17	37:24 50:14 64:20	138:1,4,6,14 139:4
9:21	68:1	correspond (1)	91:17	139:6,8,11,25 140:3
contain (1)	convoluted (1)	192:9	critical (5)	140:19,21 144:2
29:11	194:5	corresponded (2)	16:4,23 79:15,15	148:21,22 149:25
contaminating (1)	cooked (1)	134:5 140:12	166:5	150:1,3,9,21,23,25
171:12	203:20	correspondence (2)	Critically (1)	151:14 156:12
contamination (7)	COPD (1)	145:5 192:14	167:21	157:25 159:6 160:6
6:9 168:10,14,16,23	16:20	corresponds (1)	criticisms (2)	161:23 162:8 163:4
193:19 194:17	copied (1)	163:14	79:22 148:2	163:19,24 164:2,8
contemplating (2)	200:6	corroborate (1)	cropped (1)	164:11,18,21,22
139:5,7	copies (2)	127:14	58:16	165:3,8 166:10
contended (1)	199:12 200:8	coughing (1)	cross (1)	167:12,14 168:18
202:14	copy (3)	83:7	139:11	200:22 203:20,22
context (4)	129:7,9 175:18	counsel (6)	cross-product (1)	204:5,20,22,22
35:25 36:9 57:6	Corey (3)	7:20,23 172:8 178:21	124:3	205:17
196:16	3:9 7:21 8:22	191:25 210:17	cross-section (1)	date (25)
continue (1)	correct (113)	count (2)	31:7 42:14 132:1	
145:3	9:2,5,6,10,11 10:16	41:12 112:2	133:25 134:2,2,4,15	
continued (2)	10:17 11:10 13:19	counted (1)	135:23,24 136:3	
5:1 6:1	16:18 18:13,17 20:1	135:17	137:2,22,25 138:8	
continues (2)	20:6,18 22:4,12	counter-factual (1)	140:12 143:1 147:7	
197:13 202:5	24:20 25:12 26:8,10	85:19	current (4)	
Continuing (1)	26:11 29:16,20 39:3	counterfactual (1)	87:17 196:15,16,21	
88:6	39:11 40:11,18 41:4	86:7	customary (1)	
contract (2)	42:12,19 43:17,22	countries (1)	173:9	
169:14 203:17	44:10,12,21 45:1,5	81:5	cut (1)	
contradicted (1)	45:18,19 48:25 49:6	counts (2)	138:13	
176:15	49:7 50:3 51:5 52:2	160:2 182:3	cutoff (1)	
contribute (1)	53:5,10 61:15,18,25	County (3)	135:25	
169:7	62:4 63:21 65:25	207:2 210:4,23	cutoffs (1)	
contributed (1)	67:22 68:12 69:15	couple (7)	38:17	
167:15	75:25 79:19,20 80:2	24:12 77:4 83:25,25	CV (2)	
contributing (12)	85:6 87:7 89:5,17	111:9 131:18	16:12 29:4	
35:10,15 36:14,19,25	90:16 91:25 92:5	course (5)	<hr/>	
37:21,21 38:3,7,21	97:20 98:5 100:11	13:1 55:7 70:8 192:24	D	
38:22 108:8	100:14 101:7,20	205:19	D (4)	
contribution (4)	105:9 106:10	court (12)	4:1 5:1 6:1 29:6	
26:13 35:20 37:14,18	108:11 113:11	1:1 2:1 7:9,18 9:19	damages (1)	
control (6)	114:5 117:3 122:4	11:2,8 12:20 44:24	12:16	
25:10 27:3 28:10	122:24 123:9	46:17 166:3 175:13	damaging (1)	
145:19 153:21	124:15 125:6,6	courtesy (1)	20:16	
154:8	127:10,19 132:6	206:7	data (106)	
controllable (1)	138:3 146:13,15	cover (5)	4:24 34:18 41:6,8,11	
92:25	156:11 168:12,20	72:21,21,22,22 77:25	41:13,18,19 44:2,11	
controlled (1)	169:16 175:14	coverage (2)	44:20,25 45:9,16	
92:16	182:6,15,23 185:11	19:19,20	46:19,23 51:4 54:11	
convective (1)	187:1 189:2 191:24		71:25 72:6 75:8,12	

December (3) 143:6 145:15 146:15	208:3	derived (3) 38:25 122:13 123:14	detriment (2) 90:20,20	113:10 121:13 124:12 134:10
decide (2) 46:3 64:11	207:7	derives (1) 39:19	develop (2) 177:3,12	135:16 150:24 164:6 167:10,19
decided (2) 120:8 141:5	153:24 159:10	deriving (1) 39:8	developed (6) 12:3 99:6,7,8 153:22 177:17	205:23 206:8 differential (1) 48:17
deciding (1) 179:4	demonstrated (4) 76:25 82:11 152:24 204:5	describe (7) 28:6 35:19 78:10 98:10 177:13 179:6 197:19	developer (1) 67:6	different (2) 21:2 147:2
decision (1) 68:9	demonstrates (3) 180:8 181:16 192:3	described (8) 44:1 47:12 126:18 158:13 177:20 180:21 192:5 197:14	developing (1) 54:22	difficult (4) 32:23 55:25 73:17 108:3
decision-making (1) 195:16	demonstrating (1) 193:18	describes (3) 58:22 124:3 198:19	development (1) 35:10	dip (1) 78:17
declare (4) 172:6 173:1,2,9	demonstration (1) 107:13	describing (1) 30:8	deviations (1) 205:1	dips (3) 139:15,17 161:13
declared (1) 173:16	department (1) 16:6	description (5) 4:15 5:3 6:3 36:2 62:21	device (11) 35:4 67:6,11,16,21 102:2 123:16 135:17 166:19 168:22 185:23	direct (1) 190:8
decline (3) 109:15 115:25 116:1	departure (1) 206:4	descriptions (1) 148:8	devices (4) 6:13 27:21,23 195:21	directed (3) 99:1 195:23 196:3
decolonization (1) 117:2	depend (6) 35:25 51:17 79:13 107:23,24 131:11	descriptors (2) 62:21 63:19	devote (1) 22:18	direction (1) 210:11
decreased (1) 121:7	depending (1) 15:21	deserves (1) 65:17	devotes (1) 22:25	directional (2) 168:9 169:6
dedicated (1) 153:16	depends (4) 64:7,7 111:14,18	design (6) 14:14 27:20 67:10 93:14,14 107:12	diagonals (1) 124:4	directly (4) 11:14 41:12 59:5 187:23
deep (10) 35:3 49:16 53:17 55:24 56:20 104:12 107:16 121:24 157:18 166:18	depicted (1) 163:12	designated (1) 145:22	diagram (1) 70:10	disagree (2) 94:4 148:4
deeper (1) 110:5	depiction (1) 168:21	designed (2) 85:16 171:11	diameter (2) 15:14,20	disavowed (2) 109:22 203:8
deeply (1) 177:17	depicts (3) 135:4,13,14	desirous (1) 207:8	diametrically (1) 179:14	disclaimer (1) 189:7
defendant's (1) 72:10	deponent (3) 42:14 43:19 210:15	destroy (1) 84:19	dictate (1) 133:18	disclosed (1) 196:4
defendants (4) 2:11 3:8 7:22 71:13	Deponent's (3) 208:1,25 209:25	detail (2) 70:10 147:18	diesel (2) 21:6 24:3	discloses (1) 183:14
define (3) 26:1 27:16 40:7	deposed (1) 11:3	details (5) 32:6 76:14 83:16,23 156:6	differ (3) 86:22 103:3,18	disclosure (3) 173:24 182:25 196:22
defining (1) 25:19	deposition (35) 1:13 2:10 7:7,11 8:8 9:1,18 32:19 33:10 33:14 34:3 42:10,15 42:23 44:3 66:4 68:5 73:9,10 74:15 95:10 113:14 116:21 128:23 129:5 130:15 206:21 207:5,6 208:8,12 210:6,7,9 210:12	detergent (1) 182:13	differed (2) 49:14 90:4	disclosures (1) 196:12
definitely (1) 73:21	depositions (5) 32:22 33:25 41:24,25 142:23	determination (3) 45:12,20 53:13	difference (11) 76:8,20 79:24 90:7 94:9 101:2 119:19 133:4 158:17 177:19 179:12	discredit (1) 79:17
definition (3) 26:4 93:16 204:18	depth (2) 179:7,8	determine (5) 30:15 31:1 38:20 47:19 93:19	different (38) 13:12 21:7 22:15,15 35:18 55:11,12,13 63:13 69:7,13 70:13	discrepancies (1) 151:14
definitions (1) 26:15	derive (1) 41:1	determined (4) 50:2 54:1 101:22 127:3	80:7 81:5,5 86:10 94:8 97:17 100:23 101:6 102:6,11 103:9,20 104:9 108:15 111:25	discuss (3) 86:16 91:19 175:20
definitive (1) 91:12		determining (2) 39:21 152:10		discussed (8) 24:17 63:5 64:25 112:11 172:4 180:18 185:25 192:6
degrade (1) 20:5				discussing (4) 19:15 74:16 97:18 157:23
degree (1) 57:8				discussion (8)
delete (2) 208:5,5				
deleting (1)				

74:14 85:12 116:10 124:17 125:5 128:14 177:23 205:23 discussions (4) 19:2,3 41:11 61:24 disease (11) 16:8,24 17:12 23:19 23:24 24:4,11 88:10 89:15 90:15,21 diseases (2) 16:1,20 display (1) 161:5 disregarded (1) 50:6 disregarding (1) 121:6 disrupt (2) 6:13,16 disruption (4) 169:6 176:14 180:5 181:12 disruptions (1) 206:6 distorted (1) 92:18 distorts (1) 48:18 distribute (1) 150:22 distribution (1) 104:2 district (7) 1:1,2 2:1,2 7:9,9 12:18 disturbed (1) 168:9 diverted (1) 78:21 Divide (1) 123:10 divided (3) 39:10 122:1 123:6 Doctor (1) 202:17 doctors (1) 201:18 document (36) 5:11,18 26:19 28:22 61:7 63:4 71:7 78:8 84:20 122:7 128:8 129:14 132:11 135:9 136:11,14 137:13 141:20,24 142:16 143:10	146:17,20 149:14 157:9 159:13 169:20,25 170:2,13 182:17 184:20 186:20 188:20 189:20 197:2 documentation (1) 177:3 documents (2) 36:10 127:13 dog (1) 179:16 doing (8) 12:24 24:18 47:22 60:7 86:16 107:8,14 146:3 domain (1) 81:17 dominates (1) 109:5 Donor (2) 183:15,24 doors (1) 18:9 Dorien (4) 1:25 2:15 7:18 210:2 doubt (1) 79:23 downward (1) 6:14 dozens (2) 81:3 108:14 Dr (72) 7:7 8:19 28:20 33:14 34:20 46:18 63:23 72:8 76:24 94:5,6 97:14 103:21 104:3 116:16,20 117:8 124:14,24 125:16 125:24 126:1,10,13 127:11,13 130:19 136:22 138:1,5 140:2 147:1,2,6,16 148:20 151:19 152:3,22 153:5 157:21 169:14 172:5 173:19,20 176:4,5,10,20,21 177:9,21 180:15,17 180:18,19 190:17 191:15 193:12,20 198:3,4 199:16 200:2,3,3,4 201:4 202:10,10 206:4,14 draft (2) 191:7 192:6	drafted (1) 159:4 drafting (1) 85:5 drafts (1) 200:6 dragging (1) 180:17 dramatically (1) 105:19 draw (3) 47:8 136:20 197:11 drawing (1) 91:12 drawn (3) 36:6 80:5 171:2 dressing (2) 152:14 153:9 dressings (2) 152:23 153:1 drew (1) 201:19 drive (1) 206:9 drop (2) 128:1 144:8 dropout (1) 48:17 drops (1) 115:10 Drs (2) 44:7 65:23 drug (4) 98:17,22 112:20 115:3 due (2) 150:23 171:14 duly (2) 8:13 210:7 duration (1) 112:10 dynamic (2) 172:15 178:6 dynamics (8) 169:1,11,13 171:15 171:21 172:2 175:23 177:8	E E (9) 3:1,1 4:1,2,14 5:1,2 6:1,2 earlier (5) 137:8 146:15 160:14 161:25 162:4 early (5) 76:18 202:15	eliminates (1) 64:1 eliminating (1) 94:7 email (11) 5:6,8,16 6:18,21 132:20 133:2 136:21 190:16 197:12 201:2 emerging (1) 24:10 emissions (1) 6:9 emphasis (1) 144:1 emphasize (1) 53:16 employee (6) 175:24 183:22 184:6 184:14 194:11 199:11 employees (2) 191:14 199:13 encompasses (1) 19:23 endeavor (1) 206:13 ended (1) 90:3 engineering (2) 18:16 27:2 engineers (1) 27:5 England (7) 103:5,11,16,18 104:23 107:24 204:3 English (1) 103:25 enlighten (1) 162:18 enormous (2) 161:18,19 entire (4) 29:11 70:6 130:1 201:13 entirely (1) 187:8 entitled (10) 4:18 5:4,11,18 6:4,8 6:12,15 29:18 136:12 entity (2) 174:24 188:8 environment (1) 19:24
---	---	--	--	---

environmental (3) 16:22 21:5 28:3	estimates (3) 93:1 109:4 160:2	exhibit (143) 4:16,18,20,22,24 5:4 5:6,8,10,11,13,16 5:18 6:4,8,12,15,18 6:21 28:17,21,23 29:5,6,10,15,17,21 29:22 33:1,2 41:25 42:5 44:1 57:21 58:18 59:9,17 61:5 61:6,8,11,23 71:6,8 73:1 74:4 84:15,21 113:14 125:17,18 128:4,6,9,16,22 129:5,10,11,15,18 129:23 130:16,23 130:25 131:17,19 131:25 132:2,8,12 132:18 134:8,9,9,15 134:16,19 136:11 136:15 137:11,12 137:14,23 141:7,19 141:21 142:10,11 142:12,17 143:18 149:13,15 152:17 156:7,8,19 157:22 169:18,19,21 170:2 170:6,15,19,22 175:18 182:16,18 184:19,21 185:4,16 186:19,21,24 187:4 187:7,18 188:15,19 188:21 189:3,6,10 189:15,19,21,25 191:11,17,18 192:5 192:7,22,23 195:14 195:15 196:24 197:1,3	111:1 112:14 113:1 196:2 experienced (1) 111:5 experiment (1) 192:5 experiments (4) 183:21 191:12 193:12 194:9 expert (30) 4:16,20 8:23 9:4,7,12 9:14 10:13,18 11:21 13:25 15:23 18:12 18:15,18 29:12 36:10 50:4 58:25 71:11 72:10 101:11 107:7 131:14 154:7 173:12 175:21 179:4,8 182:1 expertise (12) 12:19 13:14 14:16,22 14:24 15:2 19:8 25:21 27:2 35:8 39:15 177:1	204:5 face (1) 120:25 fact (21) 31:7 51:18 56:14 62:4 74:16 78:17 88:7 89:20 107:18 115:9 120:25 132:1 136:7 141:4 150:8 160:1 166:6 173:7 192:9 195:14 201:12 factor (32) 49:16 50:5,15,16,18 51:12,15,19,22 52:1 53:12,17,22 54:2,2 54:21 55:10 56:14 56:25 57:3,5 58:3 68:16,16,18,22 87:2 87:3,13 92:19 114:5 153:10
epidemic (6) 21:22,23,25 23:16 24:8,9	estimation (1) 12:16 et (6) 5:7 40:12 55:17 65:16 69:19 205:4	event (5) 56:6 127:19 128:1 158:9,11	factors (11) 64:9,13 79:14 86:23 86:24 92:22 93:5,15 94:15,16 109:12	
epidemiologic (2) 105:21 159:17	evaluate (1) 144:3	events (7) 77:21,21 90:23 127:24 128:2 135:17 160:3	factory (4) 197:13,16,21,24	
epidemiological (9) 35:8 51:2 62:9 81:10 82:13 106:11 133:12 164:1,4	evaluation (1) 6:8	explained (1) 206:10	facts (8) 38:2 94:10 109:16 117:5 178:22 191:21 193:23 196:8	
epidemiologist (7) 22:24 27:15,17,24 37:2 38:13 89:5	eventually (1) 204:14	explore (1) 115:18	fair (7) 12:6 46:9 66:9 105:22 148:1 156:22 178:10	
epidemiologists (5) 16:8 22:2,5,17 88:21	evidence (29) 13:4 35:2 44:24 56:23 57:2,4 62:24 64:23 65:21 79:3 94:11 102:6,21 106:20 109:17 117:6 140:24 141:1 153:24 167:12,19 168:22 178:13 191:21,25 192:2 193:23 196:8 200:2	explained (1) 206:10	fairly (2) 105:17 161:16	
epidemiology (12) 13:2,13 14:24 16:10 23:21 28:2 35:17 46:1 47:21 131:15 140:3 158:23	exact (3) 36:20 208:3,4	expert (1) 7:24	false (1) 82:16	
equally (2) 155:20 188:10	examination (5) 4:4,6 8:17 97:10 206:11	explain (1) 32:25	familiar (11) 14:3 15:4,6 31:9 70:19 82:19 84:5 174:12 201:25 202:17,19	
equals (3) 136:25 137:4 151:3	examine (1) 41:12	exposure (4) 51:12,14 86:11,21	familiarity (1) 202:8	
equation (1) 123:1	examined (3) 8:15 97:8 101:16	exposure-outcome (... 48:18	Family (1) 116:21	
equations (1) 177:12	example (11) 15:11 21:22 23:16 27:20 42:21,22 87:11,12 90:25 124:9 136:23	exist (1) 121:14	far (7) 137:21 161:10 176:11 177:11,17 188:3 196:17	
equivalent (1) 67:19	examples (1) 177:6	existence (1) 32:9	Farhad (2) 5:21 175:15	
era (2) 75:5 196:21	excess (2) 6:4 36:1	exists (1) 133:23	fashion (1) 28:7	
erroneous (3) 82:14,15 161:4	exclude (1) 81:15	expect (2) 107:1 118:18		
error (3) 48:10,11,12	excludes (1) 81:7	expectation (1) 118:17		
errors (1) 205:12	excuse (7) 44:17 54:3 83:7 93:14 134:9 185:9 192:22	experience (12) 10:18 13:5 14:2 16:4 19:9 54:7 110:18,24		
ESQ (2) 3:4,9				
essentially (3) 26:7 108:22 160:2				
est (1) 165:22				
establish (1) 29:2				
established (3) 24:10 46:21 53:19				
estimate (10) 35:2 38:3,23 57:8 62:22 77:8 108:23 159:25 165:23 166:18				
estimated (2) 49:2 65:2				

FAW (1)	finish (1)	4:18 5:4,19 6:8,16	9:25	25:10 27:6,12 31:11
151:3	149:12	30:10 40:14 101:6		35:6 38:14 53:23
fecal (1)	firm (1)	101:24 118:14		59:19 62:21 65:9
30:9	12:8	150:11 171:4 191:1		74:21 83:17,21 90:6
feel (2)	first (41)	foregoing (2)	33:21 66:13,22 85:14	98:8 103:3,9,23
27:8 126:21	10:18 11:7,7 18:3	207:6 210:6	143:19 144:9	107:17 120:17
femur (2)	29:2,11,14 41:24	forest (1)	full-time (2)	140:20 185:21
5:15 144:17	48:20 51:25 67:1	84:19	146:9,21	general's (4)
field (9)	71:17 82:1 98:17	forget (2)	fully (2)	80:5,11 84:17 91:18
23:20 28:2 35:16	105:13 112:20	116:5 154:23	54:10 203:3	generalizability (2)
45:25 70:23 168:10	126:9 135:2 136:23	Forgive (1)	fumes (2)	103:15 107:23
168:14,23 169:2	138:1,16 139:10	162:15	21:6 24:3	generally (10)
fields (1)	142:1 143:18,19	form (28)	fund (6)	20:7 23:6,13 62:9
31:4	145:10,14 146:7,21	15:21 37:4 48:16	174:20 175:6,24	76:16 91:11 110:8
fight (1)	168:8 170:1 176:19	68:25 81:20 102:4	195:22,22 196:3	110:11 175:8
179:16	182:7,24 190:15,20	114:24 121:9 131:7	funded (2)	185:24
Figueroa (2)	191:7 192:17 197:6	133:15 134:13	175:1,25	generated (1)
2:12 7:12	197:11 199:6	138:18 139:20,23	funding (8)	104:8
figure (21)	fit (1)	143:7 146:16 158:3	172:13,17,24 173:1,9	generically (2)
40:1 70:25 129:19,24	93:16	158:24 160:23	174:7,9 184:9	125:11 195:19
130:5,6,14,22	five (3)	162:14 165:4 178:3	further (7)	genesis (1)
131:15,17 134:9	60:17 83:9 196:17	179:17 180:11	9:23 83:13 108:5	115:20
160:11,19,19	five-minute (1)	187:20 191:12	144:1 171:9 200:25	gentamicin (24)
163:12 167:21,25	60:13	193:22 208:6	210:17	97:22,22 98:3,3,12,15
168:1,21 169:9	five-month (1)	formal (4)	fuzziness (1)	98:21 99:3,5,6,12
185:8	76:9	141:11 143:5 146:13	66:7	99:21,23 100:6,7,10
figures (1)	flatly (1)	164:9	<hr/>	100:16,19 112:20
151:2	148:4	formed (3)	G	112:25 115:3,5
file (4)	flow (5)	145:11,13 180:22	G (1)	117:17 118:17
136:24 138:2 150:9	152:4 168:9 169:2,7	forth (2)	6:6	gentamicin-teicopla...
187:12	176:14	29:25 59:16	gained (1)	97:24
files (2)	fluid (9)	forty (2)	27:5	getting (6)
150:1,5	169:1,10,13 171:20	112:6,7	Garbashi (13)	24:19 52:5,25 99:14
filters (1)	172:2,15 175:23	found (5)	169:14 172:5 173:19	100:7 111:10
186:17	177:8 178:6	38:21 59:11 99:11	173:20 176:4,6,7	give (18)
filtration (5)	focus (13)	108:6,10	177:7,21 178:8	8:8 9:18 15:19 51:23
6:9 185:25 186:1,11	16:14,15,23 21:16,17	Foundation (1)	180:9,15 181:17	52:10 63:17 64:3
186:16	22:3 23:3,5,11,12	144:13	Garbashi's (7)	70:15 76:22 107:19
final (2)	25:9 26:8 68:13	four (11)	176:10,20 177:11,24	127:20 129:10
42:15,23	focused (3)	12:9 77:21 83:8 105:7	180:4,19 181:10	142:9 164:15 177:6
finances (1)	21:13 28:2 91:5	107:15 167:23	Gary (1)	194:15 199:8 200:9
172:10	focusing (1)	182:4 192:21	42:16	given (6)
find (6)	64:17	193:17 194:14,16	gather (1)	66:2 115:17 158:11
59:9 82:24 112:6	follow (1)	fourteen (1)	133:13	158:12 159:12,15
134:22 186:9 195:9	83:19	29:17	gathered (1)	gives (1)
finding (2)	follow-up (1)	frame (1)	58:19	27:2
84:5 108:17	26:17	98:15	Gauthier (1)	giving (5)
findings (14)	Following (2)	frankly (7)	6:10	10:25 27:9 127:23
82:17 83:5,12 91:8,14	24:9 145:5	14:7 73:15 133:8	gee (4)	150:20 157:12
92:4,4 102:20	follows (3)	148:21 176:1 178:5	34:10 77:3 106:12	glad (1)
107:20 175:21,23	8:15 97:8 181:4	186:2	118:22	163:7
176:14 200:23	footnote (3)	fraud (1)	gen (1)	glass (1)
205:16	125:20 126:1 177:22	68:2	99:15	51:8
fine (7)	forced (5)	frequent (1)	general (29)	global (1)
40:24 52:19 60:5,16	1:4 2:4 6:13 7:8 208:9	110:25	10:7 15:9,13 16:3	32:5
60:19 95:5 163:8	forced-air (13)	frequently (1)	19:10 21:18 23:20	go (26)

41:21 76:1 79:5 86:3 87:10 92:6 108:5 112:19 116:1 121:10 124:10 127:22 134:7,20 135:5 139:9 147:3 151:19 160:9 163:20 171:19 180:1,1 181:5,6 186:6 goes (8) 70:9 115:8 161:13 162:11 168:8,9 196:16 198:4 going (34) 14:19 40:5 48:20 60:1 66:6 71:5 78:5 84:14 99:17 129:10 131:10,12 137:10 139:4 141:9 142:9 149:9,10 154:17,21 159:21,24 161:20 162:9 165:11 177:13 184:18 191:20 194:22 199:23 200:8,12 202:18,21 good (7) 8:19,20 14:23 60:10 84:9 95:3 178:22 Gordon (137) 3:9 4:4,6 7:21,21 8:18 8:22 23:9 28:16 29:1 37:19 38:12 42:7 45:4,10 51:10 59:25 60:8,14,25 61:10 63:9 71:5,10 78:11 82:7 84:14,23 85:11 94:19,23 95:5 97:13 100:5 101:1,9 102:8 103:1 109:20 115:2 117:7 121:16 122:9 125:19,22 128:3,11 129:1,8,17 129:21 131:4,9 132:7,14 133:19 134:17 135:1,11 136:10,17 137:10 137:16 138:24 140:1,6,23 141:23 142:9,19 143:12,15 146:23 147:5,9,13 149:2,12,17 151:20 152:2 153:6 157:10 158:10 159:3 160:13 161:2	162:17,21,25 163:7 165:10 166:1,24 167:6 169:18,23 170:5,14,24 173:6 174:4 176:17 178:9 179:21 180:18,21 180:25 181:2,21 182:16,20 184:18 183:21 gosh (1) 195:12 gotten (1) 91:22 government (1) 24:7 government-fund... 174:24 Governor (1) 141:16 grafting (1) 183:21 gram-negative (2) 98:13 113:2 gram-positive (7) 98:22 99:7,8,10,14,22 100:8 gram-positives (3) 99:1 100:7,17 Granted (1) 206:7 grants (1) 175:1 graph (2) 136:12 138:5 graphic (1) 150:20 great (3) 13:5 70:10 156:12 greater (1) 177:12 ground (1) 101:12 group (28) 10:21 23:19 25:1,15 25:16,20 27:4 51:11 51:13,14 55:22 86:8 89:21,22 99:6,8 118:23,24 119:17 124:16 125:9 126:2	127:19,21 145:7,10 145:13,15 grouping (1) 56:22 groups (7) 16:7 24:22,24 25:22 50:25 77:22 86:21 guarantees (1) 205:10 guess (19) 11:22 12:15,21 23:5 24:15 30:19 45:22 77:4,4 131:18 132:15 155:12 157:19 159:12 172:22 184:23 186:14 188:10 195:11 guessing (3) 9:24 10:4 71:19 guys (1) 190:19	H H (3) 4:14 5:2 6:2 half (3) 71:18 109:6 206:3 Hamer (5) 6:14,17 191:4,8,12 Hamlin (2) 12:12,14 hand (11) 8:4 33:17 43:6 82:6 115:21 129:10 164:12,22 187:13 188:17 189:17 Handbook (1) 19:17 handed (1) 184:25 handing (1) 51:8 handle (1) 192:1 Hansen (1) 42:16 happen (1) 10:3 happening (3) 31:23 117:15 160:7 happens (2) 125:9 139:10 happy (1) 162:19 hard (5)	55:24 73:15 115:22 116:9 151:17 harder (1) 158:14 head (1) 34:15 head-to-head (2) 100:22 101:5 health (32) 4:22 25:21 28:4 32:5 82:19 83:1,2,5,19 84:7 88:8 89:17 104:1,23 143:23 145:25 156:13,17 164:25 172:18 174:10,18,22 175:2 175:5,7,8,9,25 176:21 178:1 179:10 Health's (2) 180:10 181:19 health-related (1) 12:17 Healthcare (1) 144:13 heard (4) 66:12,14 119:8 120:1 Heat (1) 6:4 heavily (1) 12:13 heavy (1) 80:16 held (4) 7:11 83:5,22 145:9 hello (1) 11:16 help (2) 159:2 175:12 helps (1) 129:2 hepatitis (4) 17:7,20,21 20:24 hereto (1) 210:16 hereunto (1) 207:10 heterogeneity (1) 109:10 hey (2) 106:2 119:5 Hi (1) 190:19 hidden (1) 205:13 high (11)	53:20 80:18 81:3 89:7 99:19 120:18 138:11,21 144:21 161:17 163:21 higher (7) 80:18 99:13 107:2 116:1 118:23 124:10 177:2 highlights (1) 107:9 highly (3) 111:3 112:15 147:5 Hill (2) 64:19,20 hip (5) 104:24 144:16,23 151:9 152:14 hired (3) 173:12 175:21 179:8 history (5) 66:14,23 68:3 90:25 184:17 hold (7) 22:23 32:17 82:17 83:13 84:1 139:22 191:16 holding (2) 23:18 189:17 Holford (19) 4:21 44:7 70:9,17 71:13 72:7,23 75:21 77:3 94:5,17 104:3 104:5,14 126:4 127:13 130:4 148:7 160:22 Holford's (18) 75:24,25 76:24 103:21 124:24,25 125:16,24 126:13 128:20 134:20 135:3 138:5,5 147:16 148:3 160:9 163:12 honestly (1) 32:22 honesty (1) 204:24 Hong (4) 23:19 24:7,10,16 hope (1) 188:24 Hopkins (1) 16:6 hormone (5) 84:8 87:18 88:22 89:8 90:3
---	--	--	---	--	--

hosp (1) 109:10	122:20 130:1 135:17 152:7,15	163:16 205:3 identifies (2) 160:11 172:17	16:7,21 33:11 58:23 73:14 105:1 112:7 113:17 132:8
hospital (22) 24:25 25:2,6,8 28:10 28:14 103:4,9,15,23 107:3,10 109:2,5,7 109:11,21 110:6 116:21 120:10,17 154:8	155:24 156:2 158:1 159:18,19 160:4 161:11 163:13,20 165:16 166:19 168:5,22 169:5 185:23 186:12 194:18 208:9	identify (4) 28:10 110:22 143:24 173:9 illnesses (1) 19:10 impact (23) 19:25 20:1 34:24 50:7 53:14 55:19 57:12 78:23 79:9 109:25 114:1 118:10 153:25,25 154:3,15 155:3 158:20 164:14 185:19 202:2,4,6	145:17 179:19,22 186:25 includes (3) 102:13 119:24 157:15 including (3) 5:14 23:17 205:7 Incorporated (1) 7:16 increase (5) 54:7,25 56:15 121:3,5 increased (11) 88:9 89:14 90:22 119:13,13 121:7 168:23 169:2,4,7 171:6 Increases (1) 168:5
hospitals (19) 27:10 103:4,10,17,25 104:13,24 105:4,6 107:2,14,24 108:15 108:18,22 109:4,10 143:21 154:16	Hulley (1) 88:5	impacted (1) 30:5	120:17 35:3,11 40:17 49:17 53:18 54:7,22 55:1,24 56:20 58:3
Hot (2) 107:17 156:3	humans (1) 86:5	impacts (1) 50:11	76:8 77:1 94:9 99:7
HotDog (36) 53:9,14 67:18 69:9,14 69:22 70:2,6 74:19 74:24 75:5 76:11 94:3 97:23,25 107:5 107:18 109:14 114:7,11 115:9 117:17 118:1,4,7 120:11 122:6,15,17 127:15 128:2 156:2 156:3 163:17,25 183:9	Humboldt (1) 198:7	impinge (1) 171:13	99:9,14,22 100:3,8
hotel (1) 10:23	hundred (1) 100:9	implementation (3) 134:6 140:13 156:3	102:13,16 103:22 104:2 107:3 109:13
hour (1) 95:8	hundreds (5) 31:12,14 36:4 108:14 110:19	implemented (11) 104:11,20 105:3 116:24 117:13,19 118:6,8 153:22 154:25 156:4	109:15 113:5,17 114:2,20 116:11 118:11,13 120:7,19
hours (2) 149:11 206:3	hypothetically (1) 50:23	implementing (2) 5:11 144:25	120:25 121:24 123:16 124:16 125:8 126:2 127:21
HPA (3) 143:22 144:20 145:6	<hr/> I <hr/>	implicitly (1) 93:3	129:24 133:6 136:12 145:19 150:10 151:2
HRT (11) 87:18,21 88:1,3,9,11 88:15,18 89:8 90:8 90:14	i.e (1) 146:10	imply (1) 31:7	153:20 154:1,4,8,16 156:13 157:1,17,18
Hugger (73) 1:4 2:4 7:7 10:12 12:18 35:4,8,9 49:15 53:8,14 54:20 67:2,6,11,24 69:6 69:12,18,20,20 70:4 72:2 74:17,24 75:2 75:5 76:10 94:1 98:2 101:14 102:1 102:23 103:8,10 105:7 106:25 107:2 107:4,15 108:8,19 108:24 109:14 114:16 116:12 117:16 120:6,15,15	ideal (1) 164:20	important (3) 78:18 91:21 203:14	157:25 158:16 159:12,14,19 166:19 168:6 169:8
	identical (4) 70:5 76:12,19 77:1	impressed (2) 176:1 181:21	171:7
	identification (19) 28:23 61:8 71:8 84:21 128:9 129:15 132:12 136:15 137:14 141:22 142:18 149:16 169:22 182:19 184:22 186:22 188:22 189:22 197:4	improvement (2) 175:7,8	infections (42) 5:20 15:5,7,10,23 16:5 18:1,6 30:9
		in-house (1) 7:23	53:12 55:19 56:16 57:13 99:11 102:1
		inaccurate (2) 163:4,4	102:14 104:13,20 104:24 107:16
		inaccurately (1) 126:10	113:2,5,9,13,20 114:9,11,16,22
		incidence (4) 88:10 118:23 119:3 119:18	115:15,18 120:4
		incidents (1) 118:25	121:2,7,13 122:1
		include (3) 29:4,4 143:24	136:7 150:16 152:25 158:20
		included (13) 42:14 59:6 141:14	165:17,18
			infectious (23) 15:25 16:8,11 17:2,6 20:12,19,23 21:12

21:14 22:4,6,11,11 22:14,20 23:2,18 24:4,11 28:11,14 115:18	integrity (3) 200:10,22 204:23	investigation (4) 40:15 107:8 171:1,8 investigations (1) 55:22	147:7 January (2) 5:7 116:23 JBJS (1) 150:3	207:5 208:12 210:20
K				
infer (1) 86:6	intense (1) 177:17	investigative (2) 204:2,11	Jensen (10) 55:2,14,17 56:14 57:10,22,25 58:7 59:9,15	keep (3) 43:15 166:9 185:2
inference (2) 85:4,13	intensity (1) 177:3	investigator (1) 148:24	Job (1) 1:4 2:4	Keith (1) 198:6
inferring (2) 85:18 168:20	intensive (1) 176:11	investigators (1) 149:3	jittering (3) 130:7,9,22	key (2) 20:2 118:12
influenced (1) 62:3	intent (1) 83:17	involve (3) 18:25 25:5 39:16	JNE/FLN (2) 1:4 2:4	kind (12) 18:9 33:2 63:25 80:2 94:15 107:7,11 110:21 120:6 161:9 164:2 199:9
influences (1) 172:14	interaction (1) 68:25	involved (18) 10:8 12:13 19:1 25:7 39:14 67:9 84:24 124:8 175:10	Johns (1) 16:6	knee (6) 104:24 144:16,23 151:9 152:14 157:12
info (1) 151:1	interest (17) 23:20 86:24 87:2 171:24 172:7,12,23 173:3,10,11,14,15 173:24 184:9 187:11 192:19 195:17	162:25	joint (23) 18:5 35:3,11 40:16 49:17 53:12,17 54:22 55:18,24 56:16,20 57:13,13 58:3 104:12 107:16 121:24 152:25 157:18,25 166:18 168:6	knew (3) 12:10 184:13,16
information (10) 4:8 34:17,19 49:11,19 55:4 93:24 131:19 188:2,13	interested (2) 74:22 210:19	involvement (5) 85:5 187:3 188:4,14 193:7	Jonathan (14) 1:13 2:10 3:15 4:3,16 7:7,24 8:12 63:18 97:5 207:4,13 208:8 210:5	know (133) 8:21 9:7 11:24 12:2 14:25 15:11 17:10 19:2,23 22:1 23:15 34:1,4 37:23 38:3 40:2,4 47:3,23 52:24 53:23 54:9,13 54:16,23 55:20,23 56:18 57:17 59:4,11 60:6,9,10 63:15
informed (1) 206:2	internal (1) 15:9	involves (1) 135:16	Jordan (2) 3:14 7:15	65:4 66:6,11,13,22 66:24,25 67:1,13,17
informing (1) 144:20	interpretation (2) 102:6,20	involving (3) 9:8,15 182:3	journal (8) 30:13,17,19,22 31:2 31:10,20 203:14	67:23 68:3 70:17,18
inhaled (3) 21:7,11,14	interpreted (2) 46:15 91:14	isolated (2) 90:25 94:1	journalist (2) 204:2 205:12	73:14 74:11 76:21
initial (8) 11:24 80:3 83:5,12 90:13 91:1 111:10 111:12	interpreting (1) 108:6	issue (14) 10:22 25:22 26:3 58:1 74:15 90:2 118:19 120:14,22 155:7 163:5 180:16 186:11,16	journalists (1) 204:11	77:12 79:4,5 81:4
initially (2) 32:13 79:18	interrupted (3) 30:9 93:13 97:18	issues (17) 12:17 13:6,7,10 14:15 14:17 19:15,20 21:4	journals (8) 31:10,22 32:4 110:16 110:19 196:11 203:13 205:19	83:21,21 94:25 98:9
initiate (1) 20:17	interval (10) 77:7,17,25 78:2,4,13 78:15 111:4 126:16	25:18 27:2 37:10 48:4 53:2 148:23 185:22 205:5	judgment (9) 39:17,23 53:22 54:9 54:19 85:12 178:7 178:14 192:12	104:7,18,22 105:5
Initiative (2) 88:8 89:17	intervening (1) 11:12	Item (1) 40:10	judgments (2) 13:3 93:23	105:21 108:1,1
insight (1) 27:9	intervention (5) 5:13 91:2 102:12 115:23 116:2	items (2) 40:8 73:3	July (20) 1:15 2:14 6:22 7:1,13 97:1 132:5 134:11 134:16 138:17 139:6,9,10 141:12 142:25 147:7 198:2	109:9 111:8,10
instability (3) 157:5 158:1,6	interventions (3) 120:9,16 121:1			112:17 114:13
institute (1) 144:4	intrinsic (1) 161:22			116:4 125:4,5,10
instituted (1) 116:22	introduce (2) 7:20 50:1			127:23 129:3 133:9
institutes (14) 172:18 174:10,17,19 174:22 175:2,5,9,25 176:21 178:1 179:10 180:10 181:18	introduction (2) 8:21 85:3			133:23 136:6
institutions (1) 30:10	invalid (2) 45:25 46:6			138:21 140:4 141:7
INSTRUCTED (1) 4:11	investigate (2) 30:21,24			142:14 143:12
insult (1) 18:8				147:4,6 148:13,19
				148:21,25 153:12
				153:13 154:8,24
				155:23 156:1,6
				158:5,20 161:3,19
				161:20,22,25 170:1
				174:13 175:15
				176:8,22 178:17
				183:19 186:11,14
				186:15 187:11

188:3 189:16	70:10	levels (1)	1:5 2:5 7:8 8:24 9:5	looks (6)
190:21 192:18	lead (3)	12:22	10:9,15,19 11:6	34:10 136:1 161:9
193:3 194:4,22	9:18 12:16 188:13	Liability (4)	12:8,18,19 71:14	163:21 183:18
199:6,14 200:17	leads (7)	1:4 2:4 7:8 208:10	172:9 173:13,22,25	205:17
202:9,25 203:2,16	3:14 7:15 55:8 72:24	light (1)	175:10,13 208:11	lop (1)
203:20 206:16	145:19,21 159:17	limitations (1)	little (10)	138:15
knowledge (8)	Leaper (1)	107:8	29:21 46:12 52:5	Los (8)
109:24 152:11 188:16	6:11	limited (4)	66:14 70:11 116:9	1:14 2:12 7:1,13 97:1
189:11 191:10	learn (4)	28:7 56:5 112:17	142:13 147:23	207:2 210:4,23
192:8 193:6 194:24	16:9 32:8 114:10,15	line (18)	184:16 201:21	lost (2)
known (6)	learned (2)	35:6 38:17 98:17	liver (1)	59:22 70:14
12:7 51:17 53:23	32:10 75:16	112:20 135:18	17:7	lot (15)
91:15 146:1 197:18	leave (1)	138:11,21 156:20	local (1)	10:5 13:2 18:11 21:3
knows (1)	178:5	156:24 157:4,8	144:3	61:1 73:13,14 89:6
192:1	lecture (1)	158:7 161:6,9	long (7)	101:12 106:2
Kong (4)	89:2	163:13 174:14	9:21 13:20 32:12	142:14 158:14,18
23:19 24:7,10,16	led (3)	208:14 209:1	111:1 122:10	164:7 172:23
Kumar (4)	11:5 49:1 54:14	lines (1)	204:13,13	low (4)
6:6,11 42:22 43:19	left (3)	111:6	79:4 105:17 161:16	79:4 105:17 161:16
Kurtz (3)	67:23 153:17 206:3	link (1)	163:20	163:20
155:6,9,11	legal (1)	167:19	lower (7)	38:11 107:16 121:1
<hr/>	7:16	linkage (2)	125:14 126:24	125:14 126:24
L (1)	legend (1)	105:14 106:15	150:12 162:3	lucrative (1)
6:10	183:13	linked (2)	203:17	203:17
labelled (1)	Legg (22)	79:18 93:15	luncheon (1)	95:9
7:6	6:14,17,19 182:14	list (23)	lung (12)	119:11,12
labs (1)	185:12,13 186:24	32:23 33:9,16 40:11	16:20 80:4,15 81:18	
197:23	188:25 190:17	41:22,24,25 42:10	81:23 105:17,23	
lack (2)	191:4,8,11,15 192:4	43:1,3,4 44:4 57:24	106:3,13 118:24	
205:1,2	192:16 193:8,12,13	legibility (1)	119:11,12	
laid (3)	194:8,9,10 200:4	58:9,18,20 73:2	Lydel (1)	198:5
58:13 167:21 169:8	90:6	113:15 170:7	<hr/>	M
Laminar (2)	Leland (1)	179:19 185:5 190:3	M (2)	
152:4 191:3	198:6	190:9	4:16 7:23	
Lancet (8)	length-wise (1)	listed (12)	M.D (13)	
201:18,22 202:10	75:18	40:10 43:18 57:21	1:13 2:11 4:3,16 6:11	
203:12,24 204:1,9	lengthy (1)	68:6 74:4 113:14	6:11,19 8:12 97:5	
204:13	177:15	170:15 174:8	207:4,13 208:8	
large (7)	let's (27)	181:25 185:8 186:4	210:5	
28:5 83:13 87:22	15:15 16:14 18:22	191:3	M.E (1)	
119:10 132:8	27:14 40:7 41:21	listing (2)	6:11	
137:21 149:18	51:20 52:24,24	29:22 44:2	M.S (1)	
largely (2)	58:14 60:12 71:4	lists (2)	4:16	
174:25 195:8	84:4,4 94:20 112:19	167:23 182:4	ma'am (1)	
larger (1)	121:17 134:20	Litchy (1)	191:19	
16:7	141:5 151:19 160:9	6:11	magic (1)	
lawsuits (1)	163:8 167:10	literally (1)	205:10	
202:12	168:13 180:1 181:5	81:3	magnitude (6)	
lawyers (7)	197:25	literature (16)	36:1 37:13 65:14	
9:21,25 10:21 11:17	letters (1)	45:15 55:16 57:11	121:2,5 167:5	
202:11 203:18	144:19	58:23,24 59:2,6	main (2)	
204:4	level (9)	62:9 154:6 155:3,18		
lay (1)	25:12,14 48:23 49:2	166:17 168:25		
167:19	64:4 78:20 127:4	185:4 199:9 204:15		
lays (1)	151:4 177:2	litigation (20)		

17:22 57:22	141:21 142:17	130:19 131:24	22:15	microbiology (1)
maintenance (2)	149:15 169:21	132:9,21 133:20	15:3	
155:4,20	182:18 184:21	136:13 147:2	microorganisms (2)	
major (8)	186:21 188:21	149:19 159:5 160:4	168:17 169:5	
16:14 47:17,18,24	189:21,24 196:25	163:15,24 165:8,12	mid (1)	
48:2,21,23 51:23	197:3	165:13 166:4,12,16	161:15	
majority (2)	marketing (1)	166:20 167:4,12	middle (2)	
40:2 118:3	67:10	182:7 192:24	13:12,12	
maker (1)	marrow (3)	194:11 198:4 200:3	mike (9)	
202:13	183:15,24 184:7	200:15	5:6,8,16 6:21 7:25	
makers (2)	match (2)	McGovern's (1)	59:23 149:22 198:3	
183:9 202:13	137:5 150:7	142:23	198:14	
making (4)	material (5)	McGraw-Hill (1)	mind (4)	
55:25 137:20 193:20	34:14 43:4,9,11	19:18	34:9 52:12 95:4 98:22	
207:8	185:17	MDL (2)	mine (1)	
malfunctioning (1)	materials (29)	1:4 2:4	142:15	
152:6	10:12 29:5,8,18,23	mean (54)	minimized (1)	
Management (3)	30:5 33:8,11 40:10	15:6 20:8 21:18 22:1	92:11	
183:3,6 184:12	41:21 43:4,15,24	22:13 23:24 33:23	Minneapolis (3)	
managers (1)	57:24 72:25 73:14	38:10 40:1 41:14	3:5,10 183:15	
145:18	74:3 76:2,22 93:24	43:1,20 45:22 46:25	Minnesota (11)	
mandatory (1)	105:2 133:10 165:9	47:3 48:4,8,14 54:2	1:2 2:2 3:5,10 7:10	
145:24	169:24 170:16	54:4 55:23 56:5	10:15,19 11:6,18	
manufacturing (1)	179:20 185:5 186:4	60:13 72:4,16,19	12:8 183:15	
67:10	190:9	75:14 77:6 78:15	minor (2)	
manuscript (8)	mathematical (1)	89:4 103:14 111:15	47:19 111:21	
46:3,14 111:23	39:4	112:22 114:14	minus (1)	
112:16 133:5	matrons (2)	120:3 125:10,12	39:10	
190:20 200:23	145:19,20	138:20 140:11,20	minute (1)	
205:15	Matt (1)	158:5 159:1 160:25	135:5	
manuscripts (1)	147:7	161:19 162:5	minutes (1)	
198:15	matter (14)	168:15 174:13	60:17	
Mar (1)	20:4,23 30:6 32:17	177:15 178:17	mischaracterizes (1)	
5:16	47:5 53:22 81:25	180:14 186:4,8	37:6	
marathon (1)	90:6 99:19 117:21	196:9 203:5	misclassification (1)	
60:8	166:7 192:13,14,18	meaning (2)	56:21	
March (18)	matters (2)	45:25 47:6	mislead (1)	
4:17 30:1,2,4 44:18	9:22 117:22	meaningful (3)	157:11	
45:8,12 47:14 70:12	Mc (1)	127:2,3,5	misleading (2)	
73:25 74:4,13	166:11	means (3)	147:5,12	
101:17 152:20	McGovern (79)	18:4 22:15 59:12	misread (1)	
153:19 166:4,15,25	6:6,22 40:6,11,19	meant (1)	56:10	
mark (23)	41:2,7 44:20,25	155:10	missed (1)	
5:6,8 6:6,10,11,18,21	45:9,13,14,21 46:11	measles (1)	33:18	
40:20 44:3 61:2	46:19,20 48:24 49:9	201:5	missing (1)	
67:10 71:5 73:19	54:19 56:2 61:11,22	measured (4)	121:12	
76:7 137:10 186:8	64:25 65:16,23	87:3 92:9,13,23	misspoke (5)	
190:16 191:4,13	66:18 67:21 69:5,19	measurement (5)	32:18 122:19 123:7	
192:4,6 194:8 198:2	74:12 78:2 93:11	19:14 48:6,8,10,12	134:18 162:19	
marked (33)	94:6 97:17 101:17	mechanical (2)	misstatement (1)	
28:21,23 34:2 61:4,5	102:20 103:23	18:16 19:21	146:17	
61:8,22 71:8 84:15	104:10 107:20	Mechanisms (1)	misstates (7)	
84:21 128:4,9 129:5	108:10 113:4,8,14	168:5	138:19 143:9 148:16	
129:15 130:16	122:5 127:8 128:5	mechanistic (1)	153:2 158:25 165:5	
132:12 136:11,15	128:13,13,23	61:15	173:4	
137:11,14 141:19	129:11 130:17,19	media (1)	misstating (1)	

200:14	MRSA (7)	needed (1)	noting (1)	117:5 121:9 133:15
misunderstood (1)	117:12,17,19 118:5,7 118:9 154:25	19:5	178:14	134:13 139:20,23
71:3	multi (1)	needs (1)	notion (1)	140:9 143:7 146:16
mix (3)	205:18	135:21	36:25	147:10 148:16
4:19 5:5 40:15	multidisciplinary (1)	negative (2)	Novel (1)	153:2 154:22 158:3
MMR (4)	145:12	91:3 98:19	5:18	158:24 160:23
201:13,19 202:15	multidistrict (2)	neither (2)	November (2)	162:13,13,23 165:4
203:19	8:24 71:14	203:23 210:17	5:9,17	178:3 179:17
modalities (3)	multifaceted (1)	net (1)	number (37)	180:11 193:22
100:23 101:6 102:11	205:18	58:10	4:15 5:3 6:3 7:6,10	194:20 196:5
modality (1)	multiple (3)	neutral (1)	13:9 32:22 35:18	objective (3)
101:18	82:13 92:3 195:10	182:12	38:14 39:8 40:10,22	178:21 179:13 205:12
model (4)	multiseries (1)	never (4)	42:22 64:10,14	objectively (1)
172:15 177:8 179:3,4	128:7	36:20 41:9 68:1 119:2	75:18 80:12 82:22	175:6
modelers (1)	mumps (1)	nevertheless (1)	106:4 112:3 115:8	objectivity (1)
178:6	201:4	50:12	117:11,25 119:10	204:24
modeling (3)	N	new (6)	121:17,25 122:2	obscured (1)
169:1 176:2,25	N (7)	112:8 132:23 133:6	124:10 125:13	88:16
models (1)	3:1 4:1,2 5:1 6:1	149:9,25 198:24	128:3 153:21 158:7	observation (7)
177:4	136:25 137:3	newer (1)	170:9,16 185:5	49:14 56:6 61:16
moderate (2)	Nachtsheim (8)	152:25	199:20 206:5	63:24 80:13 118:13
62:11 80:16	5:17 6:7,20 65:22	NHS (2)	numbered (1)	159:24
moderately (10)	132:22 190:18	144:13 157:20	42:3	observational (33)
63:7,7,10,15,20 64:2	191:5 198:8	nine (3)	35:2 47:22 48:5 61:21	35:2 47:22 48:5 61:21
64:11,24 78:25	name (6)	80:13,17 138:16	61:25 64:23 79:17	61:25 64:23 79:17
126:20	7:15 8:22 25:15 176:3	nineteen (2)	80:1,7 81:12 82:10	80:1,7 81:12 82:10
moment (4)	195:9 207:11	41:25 42:10	109:2 113:5 115:13	86:4 87:19 88:3,19
8:22 57:10 70:15	named (1)	ninety-six (1)	118:19 121:15	88:23 89:6 90:3,13
125:23	210:5	58:17	123:19,20,20 124:7	91:3,8,11,13 94:14
moments (1)	names (2)	Nodding (1)	124:8,15 128:7	101:16 106:18
74:16	110:9,14	34:15	131:22 132:24	118:20 119:4 139:3
monolith (1)	narrow (2)	noisiness (1)	133:6 136:7 148:13	141:3 165:2 182:9
158:15	57:7 78:10	161:23	157:5 159:23 169:4	201:19
month (1)	nasal (1)	noisy (4)	numerical (1)	observations (1)
71:18	116:25	164:10,13,21 165:3	37:24	176:15
months (10)	National (20)	non-airborne (1)	Numerically (1)	observed (3)
54:20 75:20 111:9,16	103:25 104:23 156:13	22:11	79:4	83:18,20 119:11
138:16 146:10	156:17 172:18	noninfectious (2)	nurses (14)	obtain (1)
163:19,22,24 164:3	174:10,17,21 175:2	21:5,16	82:19 83:1,2,5,19	135:21
Mordecai (2)	175:4,5,9,25 176:21	nonsmoker (2)	84:6 89:8,12,21	obtained (2)
3:15 7:23	177:25 179:9	118:24 119:17	90:7,7 141:15	109:22 202:13
Moretti (2)	180:10 181:18	nonsmokers (3)	146:10,21	obviously (4)
169:4 171:3	183:15,24	118:21 119:9,14	O	45:11 54:13 106:11
morning (2)	nearby (2)	nonsystematic (1)	oath (3)	152:9
8:19,20	72:23 159:19	57:16	8:13 97:7 210:8	occasion (1)
mortality (1)	necessarily (2)	normothermia (2)	object (10)	34:1
105:24	45:16 50:8	155:4,21	123:24 131:7 138:18	occasions (1)
mouth (2)	neck (4)	Northumbria (4)	139:23 140:9	70:20
180:3 181:9	5:15 144:17 157:15	103:4 144:12 147:7	191:20 199:23	occurred (3)
movement (2)	157:15	198:3	200:13 202:18,21	118:4,4,7
156:23 161:12	need (7)	nosocomial (2)	objection (38)	occurring (1)
moving (10)	91:14 120:22 131:19	5:20 15:23	37:4 38:8 45:3 81:20	113:10
128:19 129:25 130:4	135:5 140:4 188:10	note (2)	94:10 99:24 100:25	occurs (1)
131:20 134:21	162:6	177:22 208:2	101:8 102:4,18	92:21
160:15,15 161:6,16	206:9	noticed (3)	109:16 114:24	October (7)
		111:24 169:17,24		137:24 138:6,9,14

139:5,16 162:2	168:4,4,18 172:16	opposite (2)	176:24	83:17,18,23 84:2
odds (31)	172:22 173:7 174:5	optimized (1)	overall (13)	111:25 113:8 122:5
36:2,5 61:20 62:2	175:9 178:10 182:7	140:18	84:1 114:1,20 115:13	127:8,10 129:11
65:15 79:7,25 81:3	182:24 183:17	order (4)	116:4 117:22 119:3	131:24 133:21
81:6,13,14,14 99:11	185:24 186:18	50:2,20 52:9 207:8	119:18 120:24	155:6,12 159:5
99:13 121:20 123:5	188:18 190:8,11,15	ordinarily (1)	154:4,16 158:21	163:15 165:13
123:12,13,17,23	194:3 197:11,25	173:16	162:10	166:12,16,17,20
124:10 125:9,14	201:12 203:15	organism (4)	oversight (1)	167:4,12 172:5
126:14,23 127:7,16	206:19	23:24 98:23 115:24	33:12	173:22 174:6,8
127:21,25 151:2,5	on-the-job (1)	116:3	ownership (1)	177:11,18 178:8
offered (5)	13:23	organism-specific (4)	146:4	183:19,21 185:17
9:12,17 100:20 102:7	once (3)	120:5,8,14,22	<hr/>	185:25 186:5,15,25
166:3	39:15,19 105:2	organisms (6)	P	188:16,25 189:12
offering (3)	ones (3)	98:13 114:9 115:19	P (3)	189:16 191:7,12
12:20 154:18 166:18	57:22 73:12 190:1	115:25,25 120:20	P.E (1)	192:24 194:10
office (1)	online (3)	organization (3)	5:21	201:22 203:7,9,15
33:17	31:20 32:1,4	19:3 164:25 174:11	p.m (11)	204:21 205:5
oh (19)	Oops (2)	organizations (1)	60:20,24 95:6,8,10	papers (21)
13:21 15:13 16:12	59:24 70:15	144:2	97:2,12 151:22	16:12 17:19 31:12,14
21:13 32:13 70:14	operating (15)	organize (1)	152:1 205:24	31:21 32:4 36:5,9
72:8 111:21 112:15	6:5,10 14:3,6,14,19	43:14	206:22	58:16 59:5 82:23
123:5 126:6 134:18	27:10 102:24	organized (1)	page (58)	83:2,12 110:8
155:1 168:1 177:24	103:19 145:21	43:15	4:3,15 5:3 6:3 29:15	111:15 185:22
179:13 190:11,15	152:5 169:6 171:10	original (5)	35:13 38:5 41:25	186:16 195:19
195:12	177:4,13	41:19 56:8 67:5 141:9	42:4,5 58:8,20,22	197:23 200:18
okay (126)	operation (1)	201:22	59:17 63:6,8 64:17	204:14
11:11 12:2 13:11	27:6	originally (1)	65:8 68:8 75:23,24	paragraph (3)
15:15,22 17:9 21:9	opine (1)	173:24	75:25 85:8,9,10,15	85:14 143:19 144:9
22:22 25:4 26:12,22	99:21	Orthopaedic (1)	122:10 125:20,21	parallel (1)
27:20 29:14 32:12	opined (1)	5:14	129:19,20 134:22	182:3
33:4 39:19 40:25	167:7	orthopaedics (1)	134:23,24 135:3	parameters (2)
42:9 43:17,23 44:14	opining (2)	40:17	142:12 143:18	14:9 58:20
44:16 46:12 51:6,20	108:12 182:22	orthopedic (5)	144:9 145:3 160:10	part (18)
52:7 54:13 58:6,14	opinion (30)	6:5 35:9 145:2,16	160:12 167:22,25	16:3 34:11 53:7 56:18
60:19 62:15 63:11	29:12 35:5,6 36:23	191:2	168:1,2 170:22,23	62:5,6 74:8 105:18
63:20 66:25 67:7	38:7 44:8,18 50:4	orthopedics (1)	171:23 172:16,16	106:19,23 128:5
68:7,13 70:16,16	53:4 56:3 62:25	18:13	182:4,24 190:15,24	136:12 166:10
71:20 72:9,24 73:6	69:25 71:22 72:3	outbreak (1)	190:25 192:23	174:9 180:22
76:6,24 78:12 85:8	73:25 74:9 75:9	28:11	208:14 209:1	185:21 196:20
92:6 97:23 98:12	93:12 100:22 101:4	outbreaks (1)	pages (4)	204:6
99:17,18 100:21	108:16 117:21,23	28:14	1:5 29:18,25 128:7	partial (2)
101:13 106:22,25	154:18 159:4	outcome (16)	paid (3)	84:16,18
113:3,25 122:15,25	165:15 166:3	37:12 50:11 51:1,16	172:8 184:2,11	participants (1)
123:3 124:13,21	167:15 171:17	51:19 52:8,19 53:12	pain (2)	89:7
125:8 126:8,12	180:23	56:19 64:9 85:18	157:15,16	participation (1)
127:6,11 128:24	opinions (11)	86:6,25 119:24	panopoly (1)	48:17
130:11,24 131:9	8:24 9:17 29:12,24	172:14 210:19	154:2	particles (10)
133:1,3 134:20	30:6 32:17 34:25	outcomes (2)	paper (77)	13:6,10 20:7,11,15,19
135:7,10,18 136:3,9	47:15 56:10 185:20	28:4 82:25	25:18 26:7 31:5 32:2	21:18,20 169:2
137:8,22,25 142:8	186:13	outdoors (1)	34:7,23,24 35:1	171:12
142:24 144:8 149:6	opportunity (1)	16:23	40:6,9 41:2,7 44:20	particular (18)
151:19 152:12,21	16:9	outlier (2)	45:21 49:21,22	19:7 21:20 31:4 43:19
153:7,12 154:14,21	opposed (6)	91:25 144:21	56:14 59:10,15	50:4 69:3 78:14
155:2 156:19	17:12 37:21 38:22	outside (4)	61:12,22 66:18	82:2,6 85:2 108:2
160:21 161:3 163:7	129:25 147:20	9:19 11:20 107:21	121:6 136:5,21	
166:2 167:7,23	179:15		149:21 154:5	

158:20 200:16	people (13)	8:7	106:6
particularly (6)	15:10 16:5 22:13	permanently (1)	populations (1)
13:7 19:5 54:7 55:25	24:15 51:11,13	139:18	28:5
79:8 82:9	62:12 99:6,22	permit (1)	portion (4)
particulate (2)	105:13 106:4	85:20	22:18,25 77:11 133:1
20:4,22	108:13 197:22	persist (1)	portions (1)
particularates (2)	perceived (1)	150:1	33:21
21:8,11	91:2	person (3)	portrays (1)
parties (1)	percent (21)	12:15 130:18 188:7	131:25
200:24	38:4,6,11,11,24 40:2	personal (1)	position (5)
partly (1)	41:2 107:1 108:9,19	153:15	23:18 26:19 176:8
88:1	123:10 144:18,18	personally (1)	178:25 184:3
partners (1)	150:17 151:4 157:2	62:12	positive (4)
11:13	161:21,21,21	personnel (5)	82:16 91:2 117:2
party (2)	163:21,22	146:2 153:15 192:15	153:25
187:22 210:18	percentage (2)	193:10 194:7	possession (1)
patents (3)	21:10 156:21	persons (1)	175:18
202:14 203:18 204:4	perfect (2)	86:8	possibilities (1)
pathogen (2)	81:10,11	perspective (1)	69:4
23:23 24:1	Performance (1)	164:7	possibility (4)
pathogens (4)	6:5	Ph.D (3)	64:1 74:25 81:7,15
23:22 25:10 26:23	performed (2)	4:21 5:21 6:7	possible (3)
27:3	108:14 122:2	pharmaceuticals (1)	33:7 51:15 68:19
patient (7)	performing (1)	195:21	possibly (1)
5:19 6:4,16 40:16	144:22	phase (1)	195:17
145:9 171:13 191:1	performs (2)	92:17	post (1)
patient-warming (1)	103:8,10	phenomenon (1)	70:12
6:13	period (75)	92:21	post-1994 (1)
patients (3)	49:15,16,24,25 53:8,9	phonetic (8)	14:17
69:20,23 143:24	54:21 56:5,16 69:6	31:21 42:17 152:4	postmenopausal (2)
patients-wise (1)	69:9,12,14,18,19	155:10 169:4,14	84:9,10
75:18	70:1,3,4,7 74:17,19	198:6,7	postsurgery (1)
Paul (4)	75:2,3,5,16,17 76:9	phrase (9)	54:8
6:6,22 198:4,14	76:9,10 93:16 94:1	35:14,21,23 36:13,19	postulated (1)
pause (3)	94:3 97:25 98:2	36:20 41:17 47:6	194:23
107:19 127:20,23	105:8 111:5,6	68:14	postulates (1)
pay (6)	115:10 116:12,13	phraseology (1)	64:20
31:15,17,20,22 32:1	117:16,18 118:1,4,7	48:3	potential (20)
75:15	118:13 122:1,3,6,16	picture (2)	47:12 48:20 49:8,25
pays (1)	122:18,21 128:2	131:16 164:23	52:10 53:23 79:13
174:21	130:2 135:16	piece (1)	82:3 93:10,20 94:7
peak (1)	142:21 150:11	35:1	107:8 110:10,14
17:16	152:7,15 158:1,15	pieces (1)	173:11,14 178:15
peaks (1)	158:16 159:23	74:12	192:19 193:18
161:10	160:4 161:11	place (5)	194:17
peer (23)	162:10,11 163:11	143:6 145:14 146:8	potentially (6)
30:7,14,16,20,22 31:8	163:13,14,16,25	146:15 177:1	20:1,16 50:10 84:13
45:15 112:13 127:9	164:4 201:16	places (1)	186:14 203:19
148:10,12,14	210:16	202:4	pour (1)
166:17 203:9,11,15	periods (7)	plaintiffs (6)	197:23
203:23 204:16,20	49:14 94:7 113:10	172:8 178:21,24	power (1)
205:3,7,9,14	121:14,24 150:7	202:11 203:18	89:8
penalty (1)	163:17	204:4	practice (4)
8:7	periprosthetic (2)	plaintiffs (6)	144:3 154:15 165:1
pending (3)	35:11 165:17	3:2 8:1 169:15 173:18	196:15
8:25 143:11 180:24	perjury (1)	175:21 179:9	practices (5)

150:24 153:21 154:9 158:21 205:1 Pradhan (1) 88:12 pre (1) 70:11 pre-chosen (1) 134:3 precedes (1) 38:2 precise (2) 188:9,11 precision (1) 57:8 precursor (1) 195:15 predicated (1) 127:6 predictor (1) 51:18 preface (1) 195:3 premise (5) 139:24 140:10 141:9 199:24 200:13 preparation (1) 12:9 prepared (2) 34:18 173:25 preparing (5) 12:13 33:9,16 51:14 202:12 presence (1) 19:5 present (3) 3:13 177:7,8 presentation (1) 112:17 presented (1) 56:8 prestigious (1) 205:11 presumably (4) 155:15 157:5 174:2 200:20 pretty (11) 14:23 51:2 65:4 81:7 84:5,7 112:12 119:3 163:3 201:12 202:2 prevail (1) 175:13 preventing (1) 102:2 previous (2) 131:11 150:12 previously (7)	61:5 97:6 105:2 128:5 137:11 189:24 196:25 prewarming (6) 155:3,7,10,12,19 156:5 price (3) 75:7,15 77:9 primarily (6) 21:16 28:2 74:12 98:13 99:1 113:2 primary (3) 75:11 76:5 113:18 principle (1) 79:12 print (2) 208:2,4 printout (6) 44:2,13 71:25 72:6 84:16 142:11 printouts (1) 41:18 prior (17) 32:16 44:8 69:17,25 73:24 74:4,9 75:9 105:15 118:5 120:10 128:16 145:22 146:18 152:12 153:13 193:6 priori (2) 77:12 103:16 priority (1) 145:1 proactive (3) 104:21 105:11 145:16 probably (21) 9:24 10:4,20,23 11:22 14:7 32:14 40:21 52:22 59:5 60:4 70:18 74:1 110:19 124:25 131:19 164:10 173:23 188:9 196:19 203:12 problem (2) 90:12 148:25 problems (2) 48:6 148:22 procedure (1) 153:19 procedures (2) 14:14 122:2 proceedings (1) 206:21 process (8)	19:3 20:12,13 111:2 112:13 146:4 205:3 205:18 processes (3) 16:11 17:12,12 product (2) 193:21 203:19 production (1) 149:19 products (5) 1:4 2:4 7:8 195:20 208:10 professional (11) 16:17 17:10,16 18:5 20:20 22:18 23:1 24:6 37:2 66:14 164:24 Professor (17) 7:24 65:22 70:17 71:13 72:12,13 94:5 104:5 126:4 128:20 134:20 135:3 147:20 148:3 160:9 160:22 163:12 proffered (1) 8:24 proffering (1) 13:15 program (6) 116:24 141:12,15 183:15,24 184:7 prompted (1) 11:20 promulgate (1) 26:14 pronounce (1) 176:3 pronounced (1) 161:10 pronouncements (1) 153:5 proper (6) 53:3 139:2 158:22,22 159:16 162:8 properly (4) 85:16,21 171:11 183:13 property (1) 82:2 prophylactic (1) 49:4 prophylaxis (2) 53:3 75:4 proposition (1) 74:22 prospective (1)	82:12 prosthetic (1) 18:5 Protection (2) 143:23 145:25 protocol (5) 133:17,20,22 140:22 140:25 protocols (3) 69:7,13 97:17 prove (1) 91:5 proved (1) 106:9 provide (6) 56:23 57:1,2,4 85:17 110:9 provided (14) 19:19 39:11,15 43:5 44:5 49:11 58:9 59:3,17 72:20 77:22 142:7 190:2 210:15 provides (2) 35:2 55:3 public (3) 26:11 31:6 175:7 publication (28) 4:22 30:8,12,14 31:24 32:7 34:20 49:19 55:3 71:22 110:4,9 110:12 111:13 112:1 148:11,14 151:15 183:22 197:13,15,21 198:17 201:17 202:9 203:11 204:22 205:6 publications (9) 20:21 31:18 36:13 58:18 79:16 110:8 195:10 196:6 205:19 publicly (2) 109:11 152:22 publish (3) 31:15,17 32:1 published (25) 17:7,23 19:18 31:2,12 31:14 40:9 45:14 46:14 82:23 130:14 131:15 132:4 134:8 141:8 156:12 159:5 172:5 174:6 184:6 199:9,21 200:5 201:17 205:17 publisher (1)	32:1 publishing (1) 197:15 PubMed (1) 59:8 pull (2) 32:5 121:20 pulled (2) 204:9,9 pulmonary (2) 15:8 16:4 purport (1) 91:8 purported (1) 44:19 purpose (2) 115:24 175:5 purposes (3) 29:24 102:12 194:6 put (9) 12:15 13:2,13 18:22 42:16 52:14 144:1 180:3 181:8 Putting (1) 57:10 puzzled (1) 46:12
Q				
				quadruples (1) 159:19 quality (12) 19:17,21,22 20:1,6 25:10,13,19 26:1,15 26:20 200:22 quantification (1) 48:9 quantified (1) 85:22 quantify (2) 167:5,8 quantitative (4) 61:24 79:12 83:23 108:23 quarrel (2) 160:21,24 quarter (3) 105:2 156:21 157:1 quarters (3) 105:7 107:15 144:11 question (69) 18:3 21:1 22:7,16 27:19 30:3 37:9,16 38:18,19 50:24 52:16 56:4 57:19 61:2 64:6 66:2

72:25 76:23 77:13	90:9	146:12 147:15,15	124:13 128:16	126:1 153:5 157:21
82:16 84:11 100:4	range (5)	147:21 155:6 159:7	132:15,16,20 133:1	refer (1)
103:6,13,14,19	15:17,17,19,20 38:14	166:4,6 170:13	133:7 136:18	40:19
104:8 105:10 107:6	ranges (1)	171:16 181:2,3	140:14 149:20	reference (11)
108:4 115:11,20	20:4	183:19 184:13	151:13 155:1	37:3 40:22 43:25 82:5
120:5,9 125:11	rare (1)	186:5 187:2 194:2	185:25 186:5 187:5	160:14 169:24
131:8,10 132:15	196:14	198:12 204:7 207:6	received (9)	170:7,7,9,11,13
134:14 137:17	rate (15)	reader (1)	97:23 98:3,3 99:23	referenced (3)
139:24 140:10,20	76:9 94:9 105:16	131:16	184:2,11 187:21,21	169:10 172:3 188:25
143:11 148:5	107:16 116:4,11	reading (36)	198:9	references (1)
149:19 154:11	119:18 122:5,15,20	34:23 64:18 65:1,8,18	receiving (1)	174:9
155:13 159:2,22	129:24 150:10	76:6 85:15 86:3,19	144:19	referred (2)
162:16 163:9 166:9	157:2 158:16	87:10 88:6,12 92:7	recess (4)	69:2 147:25
167:9 170:4 178:15	159:20	105:1 116:20 117:8	60:22 95:9 151:24	referring (9)
180:24 181:23	rates (25)	132:22 133:1,2,7	206:1	40:23 71:2 80:9
187:14 189:9 191:6	77:1 103:22,24 104:2	136:22 143:13,20	recognize (1)	137:18 163:18
191:23 194:6,15	105:24 107:3	144:10 145:4	55:11	164:22 169:12
197:6 199:24	109:13,15 114:20	149:23 151:8	recognized (1)	170:2 201:22
200:13 201:7	117:22 118:11,13	152:17 170:25	92:8	refers (2)
questioned (2)	120:19 121:13,23	183:13 184:3	recollect (1)	36:1 127:13
54:24 186:17	121:25 144:14	187:19 190:18	156:16	reflect (3)
questions (8)	154:1,4,16 156:13	198:13,20 200:18	recollection (9)	115:12 133:5 135:19
4:11 8:23 54:17 55:8	157:25 158:6 162:4	readmitted (1)	reflected (12)	115:13 129:25 131:17
148:20 165:12	202:3	143:25	156:22 163:15	156:22 163:15
174:15 204:12	ratio (26)	ready (2)	187:3,8 189:5,15	187:3,8 189:5,15
quick (7)	36:2 61:20 62:2 65:15	190:20 198:16	191:11,18 193:12	191:11,18 193:12
111:17,19,19,20	79:7 81:13,14 99:11	really (15)	reflecting (1)	regard (6)
112:12 149:24	121:20 123:5,12,14	25:5 36:22 47:2 64:7	136:6	14:3 35:1 91:15 105:5
205:20	123:17,23 124:5,10	73:13 79:13 101:24	78:5 129:2,22,22	108:20 109:19
quickly (2)	125:9,14 126:14,23	103:12 105:24	156:18	regarding (4)
50:1 112:18	127:7,16,21 128:1	111:17 114:18	4:22 32:5 46:10	4:22 32:5 46:10
quite (8)	151:3,6	147:12 166:7	204:22	204:22
13:21 40:6 83:24	ratios (4)	175:19 186:8	regards (1)	regards (1)
102:15 121:3	36:5 79:25 81:3,6	reanalyses (1)	150:2	regimen (5)
124:15 131:25	raw (11)	111:16	49:5,5 68:20,21 70:5	49:5,5 68:20,21 70:5
205:6	4:24 41:6,8,11,12	reanalysis (2)	regimens (2)	76:19 77:15
quote (6)	44:20,25 45:8,16	45:15,18	regrouping (1)	regrouping (1)
55:9 57:5,9 68:25	46:19 204:19	reason (12)	206:8	206:8
125:6 130:7	reach (1)	14:16 64:3 94:4 103:2	regular (1)	regular (1)
<hr/>	56:17	103:7 109:14 126:3	146:3	146:3
R	reached (3)	126:9 130:12 161:4	regularly (1)	regularly (1)
R (3)	166:21,22 178:16	175:11 204:8	144:19	144:19
3:1 4:20 198:7	Reaching (1)	reasonable (2)	relate (2)	17:11 21:24
raise (1)	10:20	160:8,8	related (23)	17:11 21:24
8:3	read (62)	reasons (6)	10:12,22 13:6,10	10:12,22 13:6,10
raised (2)	11:5 23:15 31:3 32:8	11:22 23:17 56:12	16:12,13 17:18,19	16:12,13 17:18,19
148:23 204:12	32:12,19 33:14,24	62:1 105:13 178:15	19:20 25:22 27:2	19:20 25:22 27:2
raises (1)	44:17 46:14 58:25	recalculation (1)		
192:18	66:4,7 68:4 71:1	127:18		
ran (1)	72:12,19,20,21,22	recall (34)		
152:23	73:4,8,10,15,18,18	11:1 31:5 34:6 55:21		
randomized (8)	73:21,22,24 74:13	56:22 57:1 75:13,22		
82:12 86:17,20 87:22	76:1,24 93:6 103:21	83:7 94:21 97:16		
88:11 89:10 90:18	103:22 116:16	98:20 113:16		
91:5	124:13,23 125:2,2	116:18,20,24 117:8		
randomly (1)	142:13 143:14	117:10 121:20		

85:20 119:25 120:6 120:9,14 182:1 183:24 185:22 187:22 195:20 205:22 210:18 relates (1) 159:8 relating (3) 21:4 61:19 72:2 relationship (4) 12:3 48:19 67:2 123:22 relationships (1) 28:3 relative (24) 39:1,2,9,16,20 40:25 62:2,23,25 63:25 64:14,16 65:2 77:1 78:2 79:7 99:13,20 100:8,16 108:10 119:13 137:19,19 relatively (4) 100:16 112:17 158:8 158:11 relevance (1) 202:22 relevant (10) 55:3,21 64:7 86:10 106:21 151:1 154:6 178:13 182:2,2 reliability (2) 106:17 110:1 reliance (3) 32:23 33:11 72:25 relied (2) 43:12 59:2 rely (4) 58:7 62:20,23 101:14 relying (3) 193:17 194:16 199:10 remain (1) 165:15 remained (1) 11:17 remember (11) 31:25 74:14 76:6,12 76:14,16 83:16,23 97:21 125:4 186:15 remembered (1) 130:6 removed (1) 92:11 render (1) 207:8 rendered (5) 44:18 47:14 71:21	72:3 171:17 rendering (8) 29:24 32:16 44:8 69:25 73:25 74:9 75:9 93:11 renders (1) 119:19 renovation (1) 10:23 repair (4) 5:15 70:15 144:17 157:15 repaired (1) 152:6 repeat (5) 18:19 21:1 115:1 120:12 193:25 rephrase (1) 194:4 replacement (7) 40:16 57:13 84:8 87:18 88:22 89:9 90:4 replacements (2) 55:19 144:24 replete (1) 82:9 replicated (2) 83:14 91:9 replication (3) 82:17 91:4,11 replied (1) 154:10 report (92) 4:16,20 13:22 29:5,7 35:12 40:9 41:20 43:12 49:4 54:15 56:8 58:21 61:21 63:3 69:17 70:1,9 71:1,12 72:7,8,12 72:15 73:1 75:24 79:15 80:5,9,11 84:17,25 90:5 91:18 92:7 101:11,17 102:22 103:21 104:3,24 107:7 108:21 116:17,18 124:19,24,25 125:16 127:6,9 128:21 134:23 135:4 137:19 147:16,25 148:3 152:3,13 153:13,19 154:24 155:23 156:1,8,17 160:10 165:5,7,22 166:4,17	167:16 170:6,20 172:3,4 173:17 175:22,22 178:11 178:20 180:16,21 182:1 183:5 185:9 186:7 187:10 199:17 204:12 199:17 204:12 144:5 153:16 reported (9) 56:15 62:2,3 65:16 69:19 103:24 105:7 122:1 127:8 reporter (27) 7:18 8:3,6 28:24 61:9 71:9 84:22 128:10 129:16 132:13 136:16 137:15 141:22 142:18 149:16 169:22 181:4 182:19 184:22 186:22 188:22 189:22 197:4 210:1,3,15,22 reporting (8) 7:16,19 103:22 107:14 144:14 145:24 150:24 157:20 reports (8) 36:10 44:6 58:25 72:10,23 105:23 142:23 147:21 represent (4) 29:3 71:11 84:15 142:10 representation (4) 44:23 45:2 193:15 200:23 representations (4) 41:10,16 194:13 204:20 represented (3) 34:20 46:17 193:9 representing (3) 29:7 191:17 199:15 request (2) 11:23 169:15 requested (4) 4:8 196:23 210:14,14 requesting (1) 145:6 require (2) 57:7 110:22 required (6) 110:9,13,17 143:22 144:5 153:16 requirement (3)	49:18 53:20 110:22 requirements (2) 104:23 157:20 requisite (3) 45:16 52:16 53:20 reread (1) 135:5 research (25) 20:21 21:3,24 23:14 23:21 24:17 43:7,9 43:13,14 55:15 57:11 104:4,15,17 135:5 researches (1) 174:20 respect (13) 18:16 64:19,21 70:22 80:15 81:18 88:22 114:22 115:15 116:2 153:14 179:3 193:23 respected (1) 31:3 respiratory (1) 19:10 responding (1) 53:16 response (3) 150:16 171:18 172:19 responsibility (2) 200:16,21 responsible (1) 88:2 restate (2) 119:8 162:16 result (11) 10:25 17:13 25:24 26:13 58:19 64:4 91:25 92:1,25 148:11 171:5 resulted (6) 9:22 25:18 58:12 109:12 183:20 194:10 resulting (1) 92:17 results (9) 50:7 56:7 88:7 89:16 107:23 109:8 146:6 168:22 171:2 resumed (2) 95:10 97:10 retracted (2)
---	--	--	--

85:23 86:1,14 87:6 89:15,24 90:14,17 90:21 91:19,22 92:2 93:6,8 97:19,25 98:4,7 100:10,18,23 101:19 102:3,16 105:19 106:3,6,9,18 106:23 108:10 112:14 113:5,10,15 114:2,3 120:11,23 121:21 122:3 123:7 123:8,11 126:14,17 127:2,8,17 130:21 132:2,5 134:10,11 138:2,17 140:25 143:6 147:22 148:15 149:13 151:20 156:9,14 157:3 161:11 163:1 166:25 167:24 168:6,11 170:20 171:21 172:18 173:11 175:13,19 178:2 179:24 182:5 182:14 184:15 185:5,10,14 186:19 188:5,24 189:1,6 190:2 193:1,4 203:13,24 204:24 205:6,13	right-hand (2) 85:14 143:19	119:13 166:18 167:8 168:5 169:7 171:6 202:15	Saito (4) 1:25 2:15 7:18 210:2	schedule (1) 206:6	57:12 71:17 72:15 75:23 84:2 104:4,15
risks (1) 165:23	salary (1) 184:11	salary (1) 184:11	science (2) 82:9 178:22	116:16 118:16	
risky (1) 191:1	Samet (30) 1:13 2:10 4:3,16 7:7 8:12,19 28:20,21	Samet (30) 1:13 2:10 4:3,16 7:7 8:12,19 28:20,21	scientific (5) 81:17 85:1,17 197:19	129:2 133:20 137:6	
Rivarox (1) 53:7	46:18 61:4,11 63:18 63:23 84:15 97:5,14	46:18 61:4,11 63:18 63:23 84:15 97:5,14	scientist (2) 178:22 179:13	140:3,4 141:5 142:1	
rivaroxaban (11) 53:3,7,11 54:1,20 55:18 56:13,16 57:2	140:2 152:3 180:17 180:18 199:16	140:2 152:3 180:17 180:18 199:16	scientists (1) 176:11	143:16 144:6 153:8	
rivaroxaban/Xarel... 56:24	200:2 201:4 206:4 206:14 207:4,13	200:2 201:4 206:4 206:14 207:4,13	scope (4) 14:22 154:17 176:1	158:17 159:13	
Robert (1) 6:10	208:8 210:5	208:8 210:5	176:11	171:23 172:1	
robust (5) 82:12 83:14 115:17 144:25 153:24	sample (1) 115:17	sample (1) 115:17	scientists (1) 86:5	183:12 184:1	
role (9) 24:14 178:12,19,24 179:1,2 186:12 194:23 200:17	sampling (1) 132:24	sampling (1) 132:24	scope (4) 14:22 154:17 176:1	190:16 198:10	
room (10) 6:5,10 14:4,6,14,19 102:24 171:10 177:4,14	San (1) 10:21	San (1) 10:21	score (2) 138:11,21	seeing (7) 74:22 83:8 128:16	
rooms (2) 103:19 152:5	sarcastic (1) 174:14	sarcastic (1) 174:14	score (2) 138:11,21	132:16 136:18	
Rothman (1) 148:13	SARS (6) 21:22,22,25 23:16 24:7,9	SARS (6) 21:22,22,25 23:16 24:7,9	seen (41) 30:7,12 32:21 34:11	143:3 149:20	
routes (1) 22:12	sat (1) 73:3	sat (1) 73:3	seen (41) 35:21,22 41:10,15	35:21,22 41:10,15	
RR (1) 39:10	saves (1) 25:4	saves (1) 25:4	seen (41) 41:18 44:9 45:8	41:18 44:9 45:8	
rubella (1) 201:5	saw (17) 15:9 34:6,7 41:20 44:12 57:17,20 65:5	saw (17) 15:9 34:6,7 41:20 44:12 57:17,20 65:5	seen (41) 70:9 71:15,21 83:4	70:9 71:15,21 83:4	
rule (2) 79:12 118:9	sat (1) 72:18 83:8,11 104:2	sat (1) 72:18 83:8,11 104:2	seen (41) 94:17 110:2	94:17 113:17	
rules (2) 77:20 78:14	saying (20) 10:4 11:16 32:23	saying (20) 10:4 11:16 32:23	seen (41) 123:22 130:11 137:2	121:11 128:18	
run (1) 59:7	says (20) 26:7 63:7 85:24	says (20) 26:7 63:7 85:24	seen (41) 136:22 137:2	130:4,5,25 131:2,11	
	S	S	seen (41) 142:12 157:1	132:18,19 137:9	
S (6) 3:1 4:2,2,14 5:2 6:2	Sacchet (1) 7:25	Sacchet (1) 143:19 144:9 145:4 149:22 151:8	seen (41) 142:12 157:1	141:2,24 149:18	
safe (2) 19:7 57:9	safe (2) 19:7 57:9	safe (2) 157:17 170:25	seen (41) 154:25	151:11,18 156:17	
safer (1) 202:14	safer (1) 187:19 190:18	safer (1) 187:19 190:18	seen (41) 157:24 172:22	157:24 172:22	
safety (2) 57:6 145:10	scanned (1) 73:7	scanned (1) 73:7	seen (41) 190:6 191:7,9 197:6	190:6 191:7,9 197:6	
			seen (41) 197:8 199:7	197:8 199:7	
			segueing (1) 205:22	segueing (1)	
			selection (3) 48:7,14,16	selection (3)	
			semantics (1) 72:17	semantics (1)	
			senior (2) 85:1 145:18	senior (2)	
			sense (4) 55:23 75:17 81:10,11	sense (4)	
			sensitive (1) 107:12	sensitive (1)	
			sent (7) 33:18 111:21 136:24	sent (7)	
			138:2 150:9 198:21	33:18 111:21 136:24	
			201:3	201:3	
			sentence (4) 35:12 38:4 39:11	sentence (4)	
			136:22	35:12 38:4 39:11	
			sentences (1) 167:24	sentences (1)	
			167:24	167:24	
			separately (2) 61:2 151:10	separately (2)	
			separating (1) 70:11	separating (1)	
			sections (1) 167:19	sections (1)	
			see (30) 33:10 47:24 55:16	see (30)	
			33:10 47:24 55:16	33:10 47:24 55:16	

series (8) 30:9 55:13 93:14 97:18 120:18 154:15 164:7,13	177:11 184:18 186:18 188:18 189:18 196:24	single (6) 15:17 58:15 80:16 91:10 101:12 165:2	somebody (10) 39:19,21 46:17 63:23 99:2,5 100:7 106:1 118:20 179:16	7:17
serve (2) 9:25 18:19	44:4 82:10 87:20 88:9 89:8,14 90:13	sir (1) 40:23	somewhat (4) 56:5 80:18 136:6 160:1	species (2) 15:19,21
served (1) 19:9	shown (3) 39:6 126:15 168:24	sit (9) 15:18 17:15 31:25 33:19 34:16 59:13 75:13 187:6 188:3	sorry (42) 16:16 21:1 22:5 23:8 24:5 27:18 31:6,16 32:25 42:4 43:10 50:22 52:12 56:7	specific (19) 16:11 19:11 21:19 34:5 66:2 74:2 76:14 79:12,21 84:4 113:13 114:22 115:18,24 116:3 120:20 153:11 180:15 181:23
serves (1) 12:12	shows (7) 46:4 156:21 161:6 168:25 169:4 191:25 200:2	site (7) 5:13,21 18:1 157:17 165:16 193:18 194:17	specifically (41) 15:24 17:6,25 18:7,16 21:14 23:1,4,11,14 23:21 24:24 25:2,11 27:12 29:24 30:23 31:9 33:25 34:13 36:9 53:25 58:11 73:22 74:20 75:22 79:21 113:16 114:8	
Service (3) 104:23 156:13,17	sic (1) 101:7	sitting (4) 27:4 70:16 73:23 175:19	sort (9) 101:11 103:6 111:7 114:25 119:7 120:12 122:17,19	15:24 17:6,25 18:7,16 21:14 23:1,4,11,14 23:21 24:24 25:2,11 27:12 29:24 30:23 31:9 33:25 34:13 36:9 53:25 58:11 73:22 74:20 75:22 79:21 113:16 114:8
serving (1) 13:8	side (3) 85:14 173:13 175:12	situation (2) 81:22 87:17	sixty (1) 150:18	116:18 119:25
SESSION (1) 4:5	side-by-side (1) 150:6	sixty-day (4) 128:19 160:15,20 161:6	sixty-day (4) 143:8 157:7 162:15 168:2 170:3 183:23 193:25	135:21 136:19 151:16 154:19,20 159:8 176:8,25 179:2 186:6
set (32) 29:25 44:2,11 51:4 54:11 59:16 63:18 64:8 68:9 71:25 72:6 82:3 99:17 124:12 125:6,25 137:2,9,18 138:4 139:6,11 148:21,22 151:14 163:4 164:8 164:21 165:3,8 174:19 189:12	sign (1) 208:5	size (6) 15:11,16,17 20:4 75:7 115:17	sort (9) 12:15 25:18 35:6 47:5 73:15 106:16 151:17 164:9 192:18	specifics (1) 11:25
sets (2) 41:18 125:5	significant (19) 22:18 50:12,20 52:9 56:9 76:8,20 85:5 90:20 109:8 119:20 127:4 133:4 135:22 138:7 152:24 153:24 154:3 159:11	skimmed (1) 33:24	sought (1) 25:25	Specify (1) 208:5
setting (2) 14:4 65:11	significantly (1) 52:17	sleep (3) 16:24,25 17:1	sound (3) 11:9 164:4 174:14	specs (1) 161:20
settled (1) 11:1	similar (8) 58:10 92:3 108:23 137:21 154:10,12 176:16 189:7	slightly (4) 136:1 150:12,22 205:23	sounds (1) 174:13	spectrum (1) 98:20
seven (3) 54:20 80:12 163:24	significantly (1) 52:17	small (7) 118:18 125:13 159:23 164:8,9,13,21	source (15) 20:3 47:13 48:2,20 49:1 76:2 142:20 172:14,24 173:1 174:7,9 184:10 188:12 189:12	speculate (1) 200:25
seven-month (4) 76:10 162:11 163:16 164:4	similarly (1) 105:11	smoke (5) 19:10,24,25 23:25 26:18	sources (10) 20:10 47:16,17,18,20 47:22,24 49:3 172:17 173:9	speculating (1) 174:3
Seventh (1) 3:10	simple (3) 38:1 64:6 148:6	smoker (1) 118:23	South (4) 2:12 3:4,10 7:12	speculation (7) 38:9 99:25 165:19 166:23 167:1 174:1
shoes (1) 153:15	simply (9) 38:22 39:4 46:5 66:8 84:12 124:3 132:25 164:8,22	smokers (4) 80:16 118:21 119:9 119:10	spaces (1) 19:4	196:7
short (1) 149:10	similarly (1) 105:11	smoking (14) 4:23 19:6 20:2 25:22 26:20 79:18 80:4 81:23 84:18 105:15 119:2,5,20,25	spend (2) 28:18 143:16	
shorter (1) 118:14	simple (3) 38:1 64:6 148:6	sole (1) 166:17	spent (1) 147:22	
shortest (1) 111:5	simply (9) 38:22 39:4 46:5 66:8 84:12 124:3 132:25 164:8,22	solely (2) 9:16 165:8	sphere (1) 177:1	
Shorthand (2) 210:3,22	simulate (1) 177:4	solid (1) 177:14	spiked (1) 157:2	
show (19) 28:20 61:4 84:14 89:13 91:9 128:4 132:7 133:13 136:10 141:19 169:18,19 176:23	simulated (1) 177:14	simulation (1) 81:17	spot (1) 60:16	
			specialist (1) 81:17	spray (1)

116:25	stated (2)	stratifying (1)	46:20,24 47:9,11	substantial (24)
spreadsheet (2)	38:4 152:22	77:10	48:5,18,24 49:9	22:25 35:10,14 36:13
5:10 137:21	statement (12)	Street (4)	50:13 51:2 54:19	36:19,25 37:20,22
ss (1)	36:16 80:2 110:6	2:12 3:4,10 7:12	55:22,24 56:2 57:10	38:2,7,16,16,21
207:1	136:21 148:20	strength (11)	61:15 63:24 69:5	39:22 40:4 52:11
SSI (10)	149:1,22 171:24	35:19 36:3 63:5,12	74:17 76:10,11	77:23 78:15 108:8
5:12 143:25 144:14	172:24,24 184:9	64:15,21 78:22 79:1	81:12 82:1,1,1,6,20	119:13 121:3,6
144:21 145:1,8,10	187:12	79:13 80:17 81:23	83:1,3,5,19 84:7	165:16,17
145:13 146:10	statements (1)	strict (1)	86:12 89:8,22 91:11	substantially (1)
156:21	183:25	37:23	91:13,21 92:12,17	38:11
stable (1)	states (9)	strike (17)	93:11 99:2 101:2,12	substantively (1)
164:11	1:1 2:1 7:9 105:25	9:13 14:12 26:13	101:17,22 102:21	86:9
staff (1)	108:13,15,18,22	27:25 30:13 58:16	103:23 106:12	successful (1)
145:23	160:25	62:7 70:2 101:3	107:10 109:2	146:8
stand (1)	statistical (13)	108:25 110:21	118:20 119:4,5,8	sufficient (3)
81:16	50:5,9 56:17 66:17	113:3 118:2 147:14	133:22 141:3,4	81:14 103:16 206:14
standard (8)	133:14 135:25	155:25,25 168:19	150:23 152:23	suggest (1)
39:9,18 45:16 51:2,4	138:15 139:2,12,15	striking (1)	163:13,14,17,20	81:9
63:19 93:2 205:1	139:17 140:8 162:7	57:8	165:2,21 166:5	suggested (3)
standards (3)	statistically (12)	strong (30)	169:3 171:21 182:8	76:17 91:17 108:6
18:20 26:1 196:15	50:12,20 52:8,17 56:8	56:23,24 57:3 62:4,11	182:10,21 183:1	suggesting (4)
standpoint (3)	76:20 90:20 92:10	62:16,17,19,24 63:3	187:3,7 188:4 189:5	79:23 87:23 93:17
162:7 164:2 167:11	119:19 135:21	63:7,10,15,16,16,20	189:15 191:18	139:25
staph (27)	138:7 153:23	64:2,8,12,24 78:25	193:10 194:8	Suite (2)
15:15,17 98:16,18,19	status (1)	80:21,23,24,24 81:6	201:19	2:12 7:12
98:21 112:21,23	144:21	82:11 84:7 126:19	studying (2)	superficial (1)
114:6,11,17,23	stay (1)	126:20	23:1 86:7	177:10
115:4,6,7,8,15	139:18	stronger (1)	stuff (3)	superficially (1)
116:11,23 117:11	stayed (1)	80:25	20:24 145:8 166:13	155:8
117:12,15,18,25	114:20	strongly (1)	subcommittee (2)	support (3)
118:3,6 171:12	staying (1)	63:15	25:16 26:22	174:21 184:2,11
stark (2)	171:23	struggled (1)	subcommittees (3)	supported (4)
177:21 179:12	steep (2)	54:5	24:20,21,23	65:20 79:3 182:25
start (23)	106:13,14	studied (2)	subgroup (1)	183:2
7:5 52:22 86:18 132:1	stenograph (1)	21:7 28:13	25:17	supporting (1)
133:25 134:2,2,4,10	210:10	studies (57)	subject (2)	151:1
134:15,15 135:23	step (2)	30:9 36:5 47:22 55:21	56:21 187:24	supposed (1)
135:24 136:3	49:12 140:11	56:1 57:4,12 79:18	subjected (1)	116:6
137:22,25 138:5,16	stickers (1)	80:1,3,6,7,13,14	83:14	sure (42)
139:16 140:12	28:17	81:3,19 82:10,13	submicron (1)	14:7 22:1 27:19 28:6
153:16 182:16	stop (1)	83:6 85:16 86:4	15:20	36:15 45:22 47:3
190:5	52:24	87:20 88:4,19,23	submission (4)	59:5 63:2 65:5
started (9)	story (3)	89:6 90:3,8,13 91:4	31:6 111:9,12 112:6	68:23 77:22 79:7
67:24 105:14,18	56:19 117:10 204:6	91:8,22 92:3 106:18	submit (2)	82:15 90:11 94:14
134:1 140:16,17	straightforward (2)	133:12 139:3	110:14 199:4	104:12,17 106:19
141:12 162:2	39:6 43:6	176:16 180:5,7	submits (1)	107:11 112:9
196:19	strains (1)	181:12,15,24,25	204:19	113:23 117:23
starting (10)	117:4	182:3,4,14 185:7	submitted (15)	119:7 121:21
73:9 105:17 135:16	strategic (1)	192:16,21 193:8,17	29:8,9,13 71:12 110:7	123:20 130:3
138:14,22 139:6,7,9	196:18	194:14,16,23	110:13,15,20 112:2	131:20,25 132:25
140:18 154:23	strategies (1)	199:16 200:5,11	198:16 199:11,17	133:8,11 143:1
starts (4)	58:9	study (101)	204:17,21,21	157:7 160:24
127:1 132:2,4 163:2	strategy (2)	22:5,10,14,19,24	subscribed (1)	167:17 178:17
state (8)	58:13,22	34:18 40:20 45:1,9	207:10	180:16 190:7
8:6 29:6 85:19 86:7	stratification (1)	45:13,13,14,21,23	subsequent (4)	197:22 199:18
207:1,5 210:3,23	63:11	45:24,25 46:6,6,11	30:4 83:6 89:13 90:18	205:21

surgeon (7) 12:23 13:16 80:5,11 84:17 91:18 145:17	system (9) 5:20 104:1,11,21 105:4 134:6 140:13 152:4 171:10	68:9 78:22 81:18 88:21 89:18,20 129:12 134:21 146:14 152:19	8:15 9:4,7,12,14 11:8 76:7 97:8 126:10 130:18 137:8 142:25 147:2,6	28:18 32:15 36:6 46:5 59:19 61:20 71:21 72:1 73:3 75:1 80:6,7 82:24
surgeries (7) 57:14 104:25 108:14 136:25 137:4 144:15 152:14	systematic (3) 57:15,18 58:5	163:11 166:9,14 173:19 180:8	testify (2) 130:14 173:13	111:17 113:15 119:1 125:25 154:3
surgery (5) 5:14 35:9 55:6 155:19 155:21	systems (9) 18:17 19:21 24:25 25:3,6,8 27:7,9 191:2	181:15,24 182:9,12	testifying (1) 10:1	159:10,15,25 177:20 205:2 206:9 206:11
surgical (17) 5:13,21 14:13,14 18:1 153:15 157:14,17 165:16 168:10,14 168:23 169:2 171:6 171:14 193:18 194:17	T	tape (1) 7:6	testimony (35) 8:7 9:19 10:25 11:21 33:22 37:7 58:15,17 73:19,21 76:6,15,16	think (125) 14:16,23 17:15 27:4 27:11 31:19 32:3 35:18,25 37:8,25
surmises (1) 172:13	T (5) 4:2,14 5:2 6:2,14	Taxpayers (1) 174:23	117:9 124:14 126:2	42:3 46:7 47:21
surprise (7) 36:12,17 59:7 112:5 114:10,13,15	table (17) 123:12,15,17 124:2 131:24 135:15	teaching (1) 164:25	126:12 127:11 128:13,15 130:10	52:12,19 55:2,21
surprised (2) 112:9 115:16	167:23,23 182:1,2,4 185:9,9 186:25 188:25 192:22,22	team (3) 145:2,12,22	130:21 132:20 141:2 146:18	57:6 62:18 63:25
surprising (4) 127:25 158:8 160:5 195:9	tabulated (1) 48:13	technique (1) 14:15	151:13 157:21 159:7,8 173:4 192:3	65:6 67:3,16,18 68:23 70:8,8,18,24
surveillance (25) 5:12 104:10,21 105:3 105:11 107:14,25 122:1 134:6 140:13 140:17,17 141:12 141:14,15 142:21 143:4,5 144:25 145:23,23 146:13 146:14,24 162:1	tabulation (2) 48:9,11	technology (3) 14:19 171:4 202:14	193:11 200:3 208:2 208:4	72:11 74:11 78:15 83:17 84:5 91:7,13 94:12 101:11 102:5
suspect (2) 9:20 125:12	tag (1) 59:19	teicoplanin (14) 97:22 98:4,24 99:4,8 99:15 100:9,17,19 115:7 117:19 118:5 118:8,9	text (10) 29:4 157:19 177:23 179:24,25 187:15 187:25 189:8 190:18 198:12	103:7,18 104:7 105:10 107:6,22
suspecting (1) 105:14	take (28)	tell (12) 54:18 62:7 63:11 66:10 73:9 114:21 123:3 162:22 167:14 174:17,17 176:18	thank (3) 8:2 59:1 65:6	108:4,20 110:3,18 112:15 115:21 116:9,25 118:12 119:1,4,8 120:1,5
sustain (1) 154:22		telling (3) 132:21 191:25 192:2	theaters (2) 27:10 145:21	124:20 126:3,10 127:3 128:18 130:5
swear (1) 33:23		temper (1) 178:16	theatre (1) 40:15	130:6 132:19 134:5
swing (1) 161:18		Temperature (3) 183:2,6 184:12	Theodore (1) 4:20	136:6 137:20
switch (4) 30:10 109:14 115:6 120:11		temporal (1) 49:25	theory (1) 88:23	140:20 141:17,18
switched (5) 107:4,17 152:23 155:24 156:2		ten (3) 32:13 34:8 196:17	therapeutic (2) 91:1 102:11	142:7 147:5,11,15
sworn (3) 192:2 193:11 200:3		term (3) 20:8 23:23 197:24	term (22) 14:19 23:14,15 24:4	147:25 148:5,8
syllable (1) 179:23		terms (22) 32:24 37:9 46:7 59:8 77:18 81:2,22 100:15 105:21	Temper (3) 14:19 23:14,15 24:4 123:23 133:25 140:16 153:20	151:12 152:16 154:10 156:15
		talk (16) 13:11 16:14 18:22 19:22 27:14 51:21 68:7 84:4 94:20 97:14 107:7 121:17	test (2) 155:20 158:7,8,15 162:14	157:20 159:21 160:14 161:4,5 162:8,17,24 163:3
		talked (4) 181:14 197:22	test (2) 148:11 151:7	164:1 165:24 167:18 172:11,13
		talked (4) 181:14 197:22	testified (14) 11:16 21:6 23:15	173:12,17 176:11 176:22 177:10
				178:18 182:1 185:21 190:9,19 191:9 195:18 196:9
				196:10,14,22 197:10,17 199:17
				199:20 200:15,19
				201:9 203:21 204:8
				204:14
				thinking (5) 65:7 147:1 155:11 160:17 201:6
				third (3) 13:5 48:7 114:16

thirties (1) 105:25	204:13 205:24 206:8,14	14:18 tracked (2) 23:16 105:25	65:13 68:11 trust (5) 5:13 116:22 144:13 144:20 145:2	58:4,12 61:14 69:1 69:4,6,13 75:1 77:21 86:21 93:22 94:6,15 97:16 100:22 101:5
thirty (2) 17:17 80:19	5:13	trained (1) 13:1	trust's (1) 145:13	102:10 110:9,14 111:25 113:10
thirty-three (1) 160:3	times (3) 9:2 167:11 199:5	training (1) 13:23	truth (3) 8:8,9,9	121:14,23 134:10 141:14 144:11
Thirty-two (1) 160:3	tipped (1) 204:13	transcribed (1) 210:10	try (10) 43:15 52:13 75:10 86:5 89:25 93:19 160:7 164:16 175:6 177:3	146:9,20 161:9 163:17 168:8 182:8 182:13 206:3
thought (16) 11:5 13:2 30:20 34:9 54:5 71:3,23,24 140:12,18 141:14 142:22 147:22 162:1 177:19 195:8	title (4) 168:7 190:25 197:12 199:19	transcript (7) 33:21 42:15,23 43:21 66:5 207:9 210:13	trying (18) 14:21 17:10 27:19 28:10 38:19 46:16 81:9 123:18 143:14 156:16 157:6 170:13 175:12 178:12,22,23 195:3 202:12	two-month (1) 49:24
thousand (1) 82:23	TKR (2) 5:14 144:15	transcripts (5) 42:11,13 44:3 73:10 73:11	TSG (2) 7:15,19	two-moth (1) 160:15
THR (2) 5:14 144:15	tobacco (17) 9:9,16,19 10:15,19 11:6,18,20 13:8 19:24 20:2 23:25 25:22 79:16,22 81:8 81:22	transfer (1) 108:17	tuberculosis (3) 17:19,21 20:25	two-person (1) 104:20
three (12) 13:11 30:8,10 77:21 81:4,5 83:8 109:4 109:10 198:15,25 203:12	tobacco-related (1) 9:15	transferability (1) 107:21	Tuesday (5) 1:15 2:14 7:1,13 97:1	type (4) 22:24 113:6,16 115:24
threefold (1) 48:5	today (25) 7:22 8:23 15:19 31:25 32:6 33:19 34:16 40:6 59:13 73:23 74:4 75:14 85:25 94:4 128:17 131:11 187:6 188:3 193:6 197:7 201:4 202:5 206:5,6,11	transition (2) 49:24,24	turn (4) 85:8 129:18 170:22 190:24	types (10) 101:6 112:24 113:9 113:19 120:20 121:6,13 158:20 159:11,14
thromboprophylact... 54:6 55:18	tobacco-related (1) 9:15	translatable (1) 89:23	turning (6) 85:10 125:21 129:20 134:24 160:12 170:23	typewriting (1) 210:11
thromboprophylax... 49:5,10 54:25 55:12 65:13 68:11,17,21 69:3,13,16,22 70:5 74:18,23 75:4 76:12 76:18 77:15 93:12 94:2,8	today's (2) 31:19,23	treat (2) 100:6 158:15	turns (1) 118:22	typical (1) 196:2
time (75) 10:3,3 11:7,7,15,15 14:5,9 18:11 25:4 29:21 30:1,2,9 45:8 49:14 54:16 55:13 60:20,24 66:5 69:19 70:2,4,4 73:15 74:2 74:17 75:2,2,16,17 90:8 93:14,15 94:6 95:2,6 97:12,18 98:15 105:8 108:19 112:10,10 115:5 118:5 121:23 130:15 139:11 141:7 147:23 150:6 151:22 152:1,22 153:22 157:6 159:14 162:1,14 163:14 164:7 166:16 178:14 184:5 186:19 199:2 199:6 201:16 202:9	told (1) 68:1	treated (2) 99:15 112:24	twenty (7) 11:12 17:17 80:19 163:19,22 164:3 196:17	typically (3) 111:1 112:23 133:17
	Tom (2) 12:12,14	trees (1) 84:19	twenty-four (2) 29:15,25	U
	top (1) 203:12	trend (2) 15:5 149:25	twenty-month (2) 162:10 163:11	U.K (3) 199:1 200:19 201:18
	topic (1) 154:6	trial (5) 87:22 88:8 89:10,13 155:6	twenty-nine (1) 80:7	uh (1) 32:10
	topics (1) 17:23	trials (6) 82:12 83:15,20 89:13 90:18 91:5	twenty-something (1) 80:14	Uh-huh (1) 119:15
	total (6) 113:5 122:2 136:25 144:15,16,16	tried (4) 29:4 33:6 79:22 82:23	two (45) 11:22 12:24 13:17,18 14:2 37:10,10 44:2 49:14 50:24 57:22	ultimately (7) 26:14 35:5 101:22 106:8 138:25 139:8 184:6
	totality (1) 178:13	trigger (1) 34:9		ultra-clean (3) 4:19 5:5 40:14
	totally (1) 150:2	trouble (1) 70:11		ultraclean (1) 27:10
	totals (1) 137:5	true (8) 10:2,7 21:15 80:22 98:8 154:5 173:7 207:9		umbrella (1) 20:8
	touch (2) 11:15,15	truly (2)		unaccounted (1) 92:1
	track (1)			unanticipated (2) 88:16,17
				unaware (1) 203:1

uncertain (1) 85:20	79:23 81:8	Van (1) 42:17	viral (1) 20:13	185:15 188:1,10,18 197:11 199:18
uncertainty (2) 85:21 93:2	unlisted (1) 137:3	variability (6) 158:12,18 159:11,22 160:6 164:3	virtually (1) 77:1	208:3,4
uncommon (3) 56:6 158:9,11	unmeasured (2) 92:21 93:5	variable (7) 86:11,23 111:3 112:15 136:6 158:4 160:1	virus (2) 17:7,20	wanted (3) 61:1 161:23 186:9
uncovered (1) 204:3	unpublished (2) 169:25 170:8	variation (2) 156:24 162:6	viruses (1) 20:18	wants (1) 94:25
undeclared (1) 171:25	unusual (2) 110:21 196:14	variations (1) 109:3	VOLUME (1) 1:5	warming (33) 1:4 2:4 4:18 5:4,19 6:4,8,16 7:8 30:11 30:11 40:14,16 49:15 67:16 100:23
underestimates (1) 93:1	unwanted (1) 92:19	varies (1) 158:7		101:6,7,18,24 102:2 116:12 118:14,15
underlying (9) 34:18 41:5 44:20,25 46:19,23 123:15 133:22 187:3	update (1) 133:5	variety (5) 9:22 15:10 19:3,19 23:17		123:15 150:11 155:7,19,21 171:4 191:1,2 208:10
understand (32) 13:14 14:21,25 17:10 41:14,22 46:17 47:2 52:16 66:12,23 69:5 69:11,12 90:11 94:18 103:6 115:20 121:4 123:18 148:7 157:7 160:7 164:17 166:2 183:9 195:2,4 195:7 201:1 203:6 204:6	updates (1) 206:10	various (12) 15:12 24:20,21 25:21 36:8 79:17 80:1 82:24,25 83:12 110:8 182:2	wait (3) 133:13 139:14,16	washed (1) 153:17
understanding (20) 11:24 13:7 30:16,18 34:23 55:5 56:11 67:4,5,7 103:17 110:5 116:11 134:4 135:2,12,14 141:11 183:6 187:7	USC (1) 206:5	vary (1) 159:14	Wake (1) 202:10	wasn't (13) 57:2 83:24,25 104:16 105:24 116:7 130:22,23 143:1 149:3 163:9,9
understood (1) 113:24	use (20) 23:23 35:8,23 47:7,10 48:3 53:3 54:20 63:19 69:2 77:19 109:22 138:4 140:4 144:2 152:25 158:2 164:10,18 173:22	useful (3) 79:8 108:21 131:16	Wakefield (6) 201:23 202:10,20 203:4 204:4 205:4	177:22
undoubtedly (1) 196:23			Wakefield's (1) 203:16	water (1) 149:5
Unfortunately (1) 202:7			wall (1) 151:7	way (44) 20:17 21:20 30:5 46:6
unidirectional (2) 6:13,16			wand (1) 205:10	48:18 50:12 52:9 56:5 58:1 59:20,25
uniform (1) 130:1			Wansbeck (21) 103:3,8,23 104:11,19 105:3 107:3,17,21	66:1 74:25 79:8 103:8,9 106:1 110:7
unique (3) 81:22 128:6 195:24			venture (1) 11:20	112:13 129:13
unit (3) 107:10 168:9 186:12			version (3) 92:20 129:24 134:8	138:13,14 139:2,4 140:2 141:1 155:5
United (8) 1:1 2:1 7:9 105:25 108:13,15,18,22			versus (10) 31:10 35:4 45:24 53:14 59:17 69:9 90:9 100:9 101:24 179:9	156:18 159:22,25 160:7 162:8 164:10 164:16,19 176:19
universally (1) 98:6			video (1) 7:16	177:25 179:14 181:22 185:19
University (1) 24:10			Videographer (10) 3:14 7:5 8:2 60:20,23 95:6 97:11 151:22 151:25 205:24	193:19 202:15 206:11 210:19
unknown (2)			videotaped (3) 1:13 2:10 7:6	ways (4) 20:17 90:4 103:20 104:9

60:25 61:12,22 129:11 134:21 149:10 159:6 182:8 weak (3) 57:3 62:10 91:12 Weakly (1) 63:16 wearing (1) 153:15 week (1) 199:2 weeks (1) 111:22 weight (1) 164:14 well-described (1) 47:23 well-known (1) 70:24 well-powered (2) 56:1,2 well-regarded (1) 70:24 went (6) 24:16 33:16 82:23 140:14 157:4 203:15 Wenzel (3) 72:14 116:16 147:25 Wenzel's (2) 72:12 116:18 weren't (3) 54:15 68:15 124:15 whatsoever (1) 189:5 WHEREOF (1) 207:10 WHI (1) 89:16 wide (6) 5:13 77:7,16,24 78:3 78:13 widely (1) 31:3 window (2) 131:21 161:6 wish (2) 111:7,7 withdraw (2) 32:18 204:1 withdrew (1) 204:10 witness (82) 8:5,10 9:4 10:1,13,19 23:8 37:5,8 38:10 45:7 51:7,8 60:3,6	60:10,17 63:4,5 78:8,9 81:21 85:10 94:12 95:2 100:2 102:5,19 109:18 114:25 121:11 122:7,8 125:21 128:24 129:20 133:16 134:14,24 135:9,10 138:20 139:21 140:11 143:8,10,14 146:19 147:12 148:17,19 149:5,7 153:4 157:9 158:4 159:1 160:12 160:24 162:15 165:6,20 167:2 170:12,23 173:5,12 174:2 176:5,7 178:5 179:19 180:13 193:25 194:21 195:14 196:9 199:22 200:15 202:19 207:10 210:5 women (7) 84:10 87:19,25 88:11 89:11,24 90:2 Women's (1) 89:16 Women's (1) 88:8 wonder (1) 155:9 wondered (1) 162:3 word (9) 35:21 40:4 46:13 63:2 77:24 82:15 158:2,5 164:10 words (13) 47:10 52:14 139:12 147:24 180:2,3,6 181:7,9,13 194:14 208:3,4 work (27) 11:13 13:8 16:10,16 16:17 17:5,16,20,25 18:5,24 19:13 20:22 21:10 23:21 25:5 28:8 70:19 111:2 112:13 146:3 164:24 175:1 183:20 197:15 200:18 204:10 worked (8) 10:14,21 11:14 12:8	12:14 13:9 36:9 66:20 working (5) 24:21,24 25:16 175:21 201:2 works (1) 206:14 world (3) 31:20,24 203:13 16:7 worldwide (1) 202:3 worth (2) 115:14 177:22 wouldn't (17) 22:23 23:10,25 36:24 45:11 84:11 91:10 99:21 100:9 107:1 124:11 143:5 147:9 157:24 158:21 173:8,8 wound (7) 5:21 152:13,23,25 153:9 171:6,14 write (1) 28:18 writing (9) 69:17,25 129:6,12 152:13 153:13 178:11,20 210:10 written (9) 11:5 28:13 36:4,18 37:15 80:2 189:8 199:11 201:17 wrong (8) 26:8 46:22,23 50:3 77:3 89:6 180:10 181:19 wrote (12) 66:5 85:13 124:18 137:19 142:2 154:24 155:23 156:1,8 166:16 170:20 183:5	yeah (38) 17:24 30:1 33:5 44:5 60:14 65:6 78:6,20 109:18 120:2 121:22,22 124:1 132:25 138:12,25 149:8,8 157:11,14 157:19 159:1 160:20 161:12 164:6 165:6,11 166:8 173:20 180:13,20,25 181:20 185:12 190:5,12 191:9 192:11 year (3) 15:8 144:24 162:4 Year's (1) 112:8 years (17) 11:12,12 12:4,9,24 13:3,18 14:2 17:17 19:16 24:12 27:5 83:9 196:17,17,17 204:2 yep (1) 108:18 yes/no (2) 123:16,16	85:3 125:13,20 126:1 137:24 138:9 138:14,17 139:5 163:21 192:23 198:22,23 1-210 (1) 1:5 1,034 (1) 123:2 1.03 (2) 126:16 127:1 1.2 (2) 78:9,16 1.36 (1) 151:4 1/2 (1) 161:21 1:15 (3) 94:22 95:6,8 1:50 (3) 95:10 97:2,12 10 (14) 5:11 6:20 38:6,11 137:12 141:19,21 142:12 143:18 152:17 156:7 170:22 171:23 172:16 10/07 (1) 137:1 10/30/2010 (1) 137:1 10:57 (2) 2:14 7:2 10:58 (1) 7:14 11 (14) 1:15 2:14 5:13 7:1,13 97:1 142:10,11,17 156:8,19 157:22 207:5 208:12 12 (8) 5:16 65:8 68:8 81:1 149:13,13,15 160:10 12.5 (2) 78:9,16 12:12 (1) 60:20 12:27 (1) 60:24 124786 (1) 1:24 12568 (3) 1:25 2:15 210:2 128 (1)
		X X (12) 4:1,14 5:1,2 6:1,2 50:24,25 51:1 52:4 52:5,18 Y Y (9) 50:24 51:1,16 52:3,5 52:8,19,20,22	0 0.0062 (1) 151:6 0.8 (6) 122:11,13 123:10,23 124:6,10 05 (2) 78:19 135:22 08 (1) 162:2 0o0 (3) 7:3 97:3 206:23 1 1 (23) 4:16 5:9 7:6 28:21,23 29:10,15 42:5,15,22	

4:24	186 (1)	5:9 6:20,22 116:23 161:17 198:2	123:4 3.5 (1) 144:18	130:16,23,25 131:17,19,25 132:2
129 (1)	188 (1)	2011 (4)	3.7 (2)	134:8,15 144:18
5:4		5:7,17 40:9 185:16		163:22
1290 (1)	6:15	2012 (5)	63:25 64:2	50 (1)
131:23	189 (1)	157:1 185:12 193:10 194:8 196:20	3.8 (18) 41:1 62:24,25 63:20	150:17 5042 (1)
13 (12)	6:18	2013 (6)	65:3,15 78:25 80:25	122:10
5:18 134:23 135:3 169:19,19,21 170:2 170:6,15,19,22 175:18	19 (4) 6:21 85:9 196:24 197:3	185:13 188:25 191:12 193:13 194:10	81:1,13 108:10 121:17 123:7,8,13	51 (2) 170:9,16
132 (1)	80:11	196:20	126:25 127:7,22	55402 (1)
5:6	197 (1)	2015 (1)	3:04 (1)	3:5
136 (1)	6:21	186:25	151:22	55415 (1)
5:8	1994 (2)	2016 (1)	3:17 (1)	3:10
137 (1)	14:11,15	42:22	152:1	6
5:10	1st (1)	2017 (10)	30 (18)	6 (12)
14 (3)	163:2	1:15 2:14 4:17 7:1,14 97:1 207:5,11 208:12 210:20	4:17 30:1,2,4 45:8,12 47:14 70:12 73:25 74:4,13 101:17	5:4 42:17 75:23,24,25 129:10,11,15,18 134:9,16,19
6:4 182:16,18	2	2094 (3)	136:4 152:20 153:19 166:4,15,25	6.53 (1)
141 (1)	2 (15)	21 (4)	30th (1)	151:5
5:11	4:18 61:5,8,11,23	8:14 97:7 210:8	44:18	601 (2)
142 (1)	123:6 131:24	128 (22) 167:22,25	31 (2)	2:11 7:12
5:13	160:11 161:21	168:3	5:7 197:1	61 (1)
149 (1)	163:12 185:5	22 (1)	5:17	4:18
5:16	198:22,23 199:17	225 (1)	32 (2)	62 (4)
14th (1)	210:20	3:4	123:2 189:25	13:9 18:20,24 24:19
210:20	199:20	24 (3)	321034 (1)	63 (1)
15 (5)	2,000 (1)	182:4 192:22,23	123:21	137:4
6:8 184:19,21 185:4 185:16	108:13	2500 (2)	3368 (1)	6th (1)
15-2666 (2)	2,200 (1)	2:12 7:12	123:21	3:4
1:4 2:4	144:23	268 (1)	3M (1)	7
15-2666 (JNE/FLN) ...	2.86 (5)	122:14	7:22	7 (13)
7:10	126:14,24 127:17,19	28 (1)	4	5:6 42:22 129:19,24
16 (14)	127:22	4:16	4 (9)	130:14,22 131:15
6:12 63:6,8 64:17	2.98 (1)	2x2 (2)	125:17 161:21,21	131:17 132:8,12,18
113:14 186:19,21	151:3	123:15 135:15	163:21 192:22	134:9,9
186:24 187:4,7,18	2000 (1)	3 (30)	4,263 (1)	7/1/2008 (1)
188:15 189:10	19:18	4:20 18:23 62:23	136:25	135:24
206:15	2004 (2)	63:22 71:6,8 122:14	4,444 (1)	71 (2)
169 (1)	84:16 92:6	123:10 125:12,18	137:4	4:20 13:22
5:18	2007 (8)	125:20,20 126:24	4:35 (1)	73 (4)
17 (12)	137:24 138:6,9,14,22	157:2,2 167:21,25	205:24	13:22 107:1 108:9,19
6:15 35:13 38:5	139:5,25 163:2	168:1,1,21 169:9	4:44 (1)	74 (6)
188:19,21 189:3,6	2008 (27)	182:1,4 185:8,9,9	206:22	38:4,11,24 40:1,2
189:15 191:11,18	104:11 105:4 132:2,5	186:25 192:22	41:2	41:2
192:5 195:15	134:11,11,16,16	198:23 199:18	49 (2)	8
18 (6)	136:4 138:10,17,23	3.0 (5)	40:10,22	8 (6)
6:18 189:19,21	139:6,8,9,10,16			4:4 5:8 61:6 136:10
191:17 192:7	140:14 141:12,18			136:11,15
195:14	142:25 143:6,21			8.33 (1)
182 (1)	144:12 145:15			126:17
6:4	146:15 162:3			84 (1)
184 (1)	2008-2010 (1)			
6:8	98:15			
1843 (1)	2009 (3)	3.05 (1)		
129:19	139:19 144:12 161:15	127:4		
	2010 (6)	3.1 (1)		

4:22

9

9 (12)

5:10 6:22 58:8,20,22

59:9,17 136:10

137:11,14,23 198:2

90071 (1)

2:13

95 (1)

151:4

97 (1)

4:6

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

4 In re Bair Hugger Forced Air) MDL No. 15-2666
Warming Products Liability) (JNE/FLN)
5 Litigation,) VOLUME II
) PAGES 211-324

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13 VIDEOTAPED DEPOSITION OF JONATHAN SAMET, M.D.
14 LOS ANGELES, CALIFORNIA
15 TUESDAY AUGUST 8 2017

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21
22
23

24 JOB NO. 128394

25 DORIEN SAITO, CSR 12568, CLR

Page 216

Page 217

1	I N D E X		
2	(Continued)		
EXHIBITS:			
4	NUMBER	DESCRIPTION	PAGE
5	Exhibit 28	Journal of Hospital Infection document entitled "Monitoring air sampling in operating theatres: Can particle counting replace microbiological sampling?" by A. Landrin, et al.	296
10	Exhibit 29	Journal of Clinical Anesthesia document entitled "Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial" by Ruken Oguz, et al.	298
14	Exhibit 30	Document entitled "Do Forced Air Warming Devices Increase Bacterial Contamination of Operative Field?" by McGovern, et al.	300
18	Exhibit 31	Augustine Biomedical + Design Research Report dated April 4, 2008 by Mark Albrecht	305
21	Exhibit 32	Kennedy Hodges L.L.P. document "Bair Hugger Warming and Peri-Prosthetic Infections in Joint Replacement Surgery: A Guide to Product Liability Litigation	309
24			
25			

Page 218

Page 219

1	LOS ANGELES, CALIFORNIA; TUESDAY, AUGUST 8, 2017
2	8:36 A.M.
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4	***
5	THE VIDEOGRAPHER: This is the start of
6	tape labelled Number 1 of the videotaped
7	deposition of Dr. Jonathan Samet in re Bair Hugger
8	Forced Air Warming Products Liability Litigation
9	in the United States District Court, District of
10	Minnesota, Case Number 152666 JNE/FLN.
11	This deposition is being held at
12	2001 North Soto Street, Los Angeles, California,
13	on Tuesday, August 8 of 2017 at approximately
14	8:36 a.m.
15	My name is Jordan Leads from TSG
16	Reporting, Incorporated, and I am the legal video
17	specialist.
18	The court reporter is Dorien Saito in
19	association with TSG Reporting.
20	Will counsel please introduce yourselves.
21	MR. GORDON: Corey Gordon on behalf of
22	the defendants.
23	MS. CONLIN: Jan Conlin on behalf of the
24	plaintiffs. With me here today is Mike Sacchet.
25	MR. GORDON: Also -- also here with me

1	I N D E X		
2	(Continued)		
EXHIBITS: (Previously marked)			
4	NUMBER	DESCRIPTION	PAGE
5	Exhibit 1	Expert Report of Jonathan M. Samet, M.D., M.S. dated March 30, 2017	221
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Page 220

1 is, Have you reviewed any materials since we last met
 2 on July 11?

3 A I've refreshed my memory concerning materials
 4 that I have looked at in the past. But with regard to
 5 absolute new materials, no.

6 Q Okay. So you didn't do any additional
 7 research in between July and --

8 A No, I did not.

9 Q -- now?

10 A No.

11 Q And you weren't -- you weren't given any
 12 additional published materials?

13 A No. I simply reviewed materials I had on
 14 hand.

15 Q I'm sorry? Did --

16 A I reviewed materials I already had on hand.

17 Q Okay.

18 MR. GORDON: And -- and we discussed this
 19 a little bit last time. But some of the materials
 20 that you listed on your Exhibit C, if I recall
 21 correctly, of your report, which we marked as
 22 Samet Exhibit 1. I'll give you a copy of it again
 23 just to refresh your recollection.

24 ///

25 ///

Page 221

1 (The aforementioned document was
 2 previously marked Exhibit 1 for
 3 identification by the reporter.)

4 BY MR. GORDON:

5 Q But some of those materials were ones that --
 6 well, strike that.

7 All of the materials on Exhibit C in your
 8 report were materials that you had available to you
 9 prior to when you rendered your decision -- your --
 10 your opinion on March 30; correct?

11 A That's right. And then there was the
 12 additional report by Augustine that was --

13 Q Okay. And there -- you know, I don't -- I
 14 don't want to spend a lot of time plowing old ground.

15 But in addition to that Augustine publication,
 16 you, I think, testified that you had read the expert
 17 reports of Holford, Wenzel, Borak. And I --

18 A That --

19 Q And I can't remember -- I apologize.

20 A Right. I'm not sure I can remember.

21 I -- I will add, actually, have read the --
 22 now the deposition of both Drs. Holford and Borak
 23 which were, I think, obtained in the interim between
 24 last month and -- and the -- that -- completion of the
 25 deposition today.

Page 222

1 Q Okay. And other than the depositions of
 2 Dr. Holford and Dr. Borak, have you read any other
 3 deposition --

4 A No.

5 Q -- since July 11?

6 Okay. And I can't remember.

7 Had you -- do you recall if you had read the
 8 expert opinion of Dr. Michael Mont?

9 A Offhand, I don't remember, no.

10 Q Okay. And, again, I don't want to replow old
 11 ground. But just -- I want to -- and -- and just so
 12 the record is clear. We talked about it before.

13 MR. GORDON: I want to mark somewhere --
 14 I'm showing you Exhibit 20.

15 (The aforementioned document was marked
 16 Exhibit 20 for identification by the
 17 reporter.)

18 BY MR. GORDON:

19 Q And ask you if this is the Augustine paper
 20 that you said you reviewed.

21 A That's correct.

22 Q And you had reviewed that initially sometime
 23 in between the time you rendered your original opinion
 24 in this case and when you were deposed on July 11;
 25 correct?

Page 223

1 A That's -- that's right. My understanding is
 2 the paper was published in -- in the interim following
 3 the preparation of my expert report.

4 Q And since July 11, you've -- you've gone back
 5 and rereviewed this paper; is that right?

6 A Well, I've -- I've refamiliarized myself with
 7 this and other materials.

8 Q Did you review any other materials in
 9 connection with the -- Exhibit 20?

10 A Other materials specifically, no.

11 Q Okay. And nothing about any of the hospitals
 12 that were involved or any testimony of Dr. Augustine or
 13 anything like that?

14 A No, I have not.

15 Q Okay. We'll -- we'll come back to that.

16 You -- and -- and correct me if I'm wrong.

17 But you have not -- it was not listed on your
 18 Exhibit C, the deposition of Dr. Augustine.

19 So as of March 30, you had not read
 20 Dr. Augustine's deposition?

21 A Not -- not that I recall, no.

22 Q Have you -- and have you read it subsequently?

23 A No.

24 Q Okay. All right. I want to step back and --
 25 we'll pull back about 50,000 feet and just talk about

Page 224

1 the -- the scientific process that -- that you have
 2 employed in -- in this case.

3 You -- as epidemiologist, you follow certain
 4 objective approaches to the -- the materials that you
 5 deal with; right? That was a poor -- that was a poor
 6 question.

7 There -- there's a -- there's a --
 8 there is a methodology that you, as an epidemiologist,
 9 follow in order to arrive at conclusions or opinions
 10 about causal relationships; is that correct?

11 A Well, I guess I would say that my review of
 12 the materials reflects not only my training in
 13 epidemiologist, but in medicine, my broader
 14 understanding of the -- the lung, of air, of movement
 15 of particles in air, things that I've worked on in my
 16 research.

17 So, yes, I -- I interpret the epidemiological
 18 evidence, but I try and put it in the broader context
 19 of biology, clinical path, and physiology, and so on.

20 Q And -- and I -- and I was asking kind of a big
 21 picture question.

22 That's generally how you approach issues of
 23 epidemiology and -- and -- and health-related outcomes;
 24 right?

25 A Yeah.

Page 225

1 Q You just don't look at an epidemiological
 2 study. You try to look at other lines of evidence;
 3 right?

4 A Right. I guess I would -- if you'll excuse
 5 me, I would probably rephrase things and say that I
 6 approach questions that are relevant to public health,
 7 population health, and that epidemiology is one of the
 8 research methodologies used to generate evidence that
 9 is relevant to public health.

10 Q In the past, you have been critical of those
 11 who contend that epidemiological studies are prone to
 12 generating false positives; is that correct?

13 A I've been involved in some statements
 14 concerning -- I would say sort of general comments
 15 about epidemiology and the validity of results and how
 16 they may be subject to any number of problems,
 17 including, quote, "false positives."

18 MR. GORDON: Let me show you what's been
 19 marked as Exhibit 21 just to kind of tee this --
 20 tee this up, and we'll plow through it.

21 The aforementioned document was marked
 22 Exhibit 21 for identification by the
 23 reporter.)

24 BY MR. GORDON:

25 Q This is -- this is a paper -- let's say a

Page 226

1 commentary that you co-authored in 200- --

2 MS. CONLIN: -9.

3 BY MR. GORDON:

4 Q -- 9; is that right? 200- -- yeah, 2009.

5 A Correct.

6 Q Okay. And this was something that you and
 7 your -- and all -- and the other authors wrote in
 8 response to a publication that was simplistic -- and I
 9 realize I'm being very simplistic. This was
 10 essentially taking the position that observations by
 11 the epidemiological studies are fraught with false
 12 positives.

13 A This was written in response to several --
 14 several papers that posed this sort of too strong
 15 generalization in the view of the author -- co-authors
 16 and myself that there's a generic problem with false
 17 positives, correct.

18 Q And you -- and correct me if I'm wrong. But
 19 you -- part of your opinion is based on your conclusion
 20 that the McGovern paper does not represent a false
 21 positive; is that correct?

22 A Well, the McGovern paper is certainly part of
 23 the evidence that I considered. And to the extent
 24 that the P value is less than .05, that's a helpful
 25 indication that the results are not arrived by chance

Page 227

1 alone.

2 And then of course since the McGovern paper,
 3 there's been a second report that essentially
 4 corroborates the -- the findings in other hospitals.

5 Q You're talking about Exhibit -- the Augustine
 6 publication?

7 A Yes, I am. Yes.

8 Q So -- and -- and I -- so specifically my
 9 question with McGovern is, Your opinion is predicated
 10 in -- at least in part on the -- your determination
 11 that the McGovern findings were not -- do not represent
 12 false pos- -- a false positive --

13 A That's --

14 Q -- is that correct?

15 A That's correct, essentially.

16 Q And you -- have you similarly concluded that
 17 the Augustine publication is not based on a false -- or
 18 does -- is -- is not a false positive?

19 A Well, again, yes. And with two papers that
 20 corroborate each other, I think the likelihood that
 21 both are, quote, "false positives" diminishes.

22 And there's -- you know with -- P value is an
 23 assessment of the role of chance. There are other
 24 ways to generate false positives. But with two papers
 25 with quite -- quite similar findings, I think the

<p style="text-align: center;">Page 228</p> <p>1 strength of evidence from the epidemiological side 2 has -- has grown.</p> <p>3 Q Okay. And I -- I want to go back to 4 Exhibit 21, your -- your commentary on a -- on a paper 5 about --</p> <p>6 Who is the main author on that?</p> <p>7 A Bafeda [phonetic].</p> <p>8 Q Bafeda.</p> <p>9 -- Bafeda's paper on false positives. And I 10 want to -- and I -- you know I understand this paper 11 was written generally, so I want to understand if some 12 of the principles that you articulated here are 13 principles that you believe you have applied in coming 14 to the conclusions and opinions that you offer in this 15 case.</p> <p>16 For example, on -- on the first page in the 17 middle paragraph -- or the middle column, you say 18 (reading):</p> <p>19 "It is well-known that observational 20 epidemiological studies may be affected 21 by various biases that can impair their 22 validity and that are generally not 23 present in experimental investigations."</p> <p>24 You -- you still agree with that 25 statement, don't you?</p>	<p style="text-align: center;">Page 229</p> <p>1 A It's a reasonable statement, yes. 2 Q And you were -- and that was something you 3 were considering when you evaluated both the McGovern 4 paper and then the -- the Augustine paper; is that 5 correct?</p> <p>6 A That's correct.</p> <p>7 Q Okay. And you go on to say that (reading): 8 "Critical scrutiny of epidemiological 9 studies covering all potential sources 10 and mechanisms of biasness" -- or -- 11 "biases is indispensable." 12 You still agree with that?</p> <p>13 A Yes, I would.</p> <p>14 Q So is that the appropriate -- 15 Would -- would -- would you say that that's 16 the approach you used here in re- -- reviewing the -- 17 the epidemiological component of the McGovern paper and 18 the Augustine paper? In other words, that -- that you 19 critically scrutinized them and covered all potential 20 sources and mechanisms of bias?</p> <p>21 MS. CONLIN: Well, I'm going to object to 22 the form of the question. This report is based on 23 McGovern. He indicated that he has reviewed the 24 Augustine paper subsequent to his opinions in the 25 case. And you've got a premise in the question</p>
<p style="text-align: center;">Page 230</p> <p>1 that his opinion is based on both.</p> <p>2 THE WITNESS: Sorry. Can you restate the 3 question.</p> <p>4 BY MR. GORDON:</p> <p>5 Q When you reviewed the McGovern paper -- we'll 6 start with that one -- you -- you considered that a 7 critical scrutiny of it covering all potential sources 8 and mechanisms of bias was essential -- or -- excuse 9 me -- indispensable; right?</p> <p>10 A Well, that -- that's a statement here. I 11 mean, I think in my expert report I review potential 12 limitations of the McGovern report and particularly 13 around the issue of confounding and do describe why I 14 do not consider the results to be attributable to 15 confounding.</p> <p>16 Q And, again, I don't want to plow a lot of 17 the -- the ground we did in July.</p> <p>18 But the -- the confounders that you considered 19 in your critical scrutiny of the McGovern paper were 20 limited to what was disclosed in that paper; right?</p> <p>21 MS. CONLIN: Objection; it misstates his 22 testimony.</p> <p>23 BY MR. GORDON:</p> <p>24 Q And if it does, that's -- that -- please tell 25 me what I'm missing.</p>	<p style="text-align: center;">Page 231</p> <p>1 A Well, I mean, first off, they were potential 2 confounders. Not all factors are necessarily 3 confounders. They were potential confounders. And I 4 considered the possibility that they were confounding 5 in association -- observed with the use of the Bair 6 Hugger device.</p> <p>7 Q But the confounding factor -- the potential -- 8 excuse me. Strike that.</p> <p>9 The potential confounding factors you 10 considered were only those that were actually disclosed 11 in the publication itself; correct?</p> <p>12 A I think if the comment -- of course I 13 considered the potential confounders. Discussed those 14 that were highlighted in the publication.</p> <p>15 If the question is, rather, quote, "unknown 16 confounders," I'm not sure what -- what they might be 17 given the close temporal alignment of the Bair Hugger 18 and the conductive warming time periods.</p> <p>19 Q Well, again -- again, I don't want to -- we 20 spent a lot of time on this in -- in July.</p> <p>21 But there were -- we were talking -- there 22 were a number of factors that we discussed that you -- 23 that were not disclosed in the paper that I -- and 24 correct me if I'm wrong -- that your testimony 25 indicated that you had not been aware of or considered</p>

<p>1 prior to rendering your -- your opinion on March 30. 2 For example, the -- a MSSA screening or repair of a 3 malfunctioning laminar flow ventilation system in one 4 of the operating theaters, things like that. 5 Do -- do you recall that -- 6 A I'm -- 7 Q -- generally? 8 A I'm -- I'm aware that there were other 9 changes being made within the healthcare system to 10 address surgical site infections. 11 Q And you had not focused -- or -- strike that. 12 Prior to rendering your decision on March 30, 13 you had not considered those factors insofar as they 14 were not mentioned in the McGovern paper itself? 15 A Right. Yeah. No. I think I said on my 16 expert report what factors I explicitly considered. 17 Q And one of the things that the McGovern paper 18 mentioned was that they did not factor in all 19 patient-specific considerations. 20 Do you recall that? We -- we can go to the 21 paper, but one of them was fitness for surgery. 22 Diabetes was another one. A couple things like that. 23 Do you recall that? 24 A Well, the analysis was conducted at the level 25 of contrast and what happened, two time periods and</p>	<p>1 not -- not around specific individuals. 2 Q Okay. Would you agree with me that in -- 3 in -- in doing a proper observational study on deep 4 joint infection rates, that -- that it's important to 5 consider patient-specific factors to -- to determine if 6 the two cohorts you're looking at have any potential 7 confounders in the -- the patient demographics? 8 A I think that one of strengths of the McGovern 9 study was, in fact, the close proximal temporal 10 alignment of the two time periods. I mean, it seems 11 somewhat unlikely that over the course of a transition 12 period of two months there would be major changes in 13 patient demographics that would affect -- affect risk. 14 MR. GORDON: Let me show you Exhibit 22. 15 This is a 1989 publication -- or -- excuse me -- a 16 1990 publication by Gordon, et al., and the senior 17 author is William Jarvis. 18 (The aforementioned document was marked 19 Exhibit 22 for identification by the 20 reporter.) 21 BY MR. GORDON: 22 Q Have you seen this paper before? 23 A No, I have not. 24 Q And you -- you know that -- that Dr. Jarvis is 25 one of the experts retained by plaintiffs in this case?</p>
<p>1 A Yes. 2 Q Have you -- had you read his report? 3 A I did read Dr. Jarvis's report. 4 Q And you consider him an expert in infectious 5 diseases; correct? 6 A He seems very well-qualified, yes. 7 Q And you consider him an expert in 8 investigation of -- of hosp- -- nosocomial infections 9 specifically; right? 10 A He has -- he has a very likely record of such 11 research. 12 Q Okay. And, you know, again in the interest of 13 time, I don't expect you to study this in -- in detail, 14 but I -- and certainly feel free to read the -- 15 whatever you want. But the abstract, you know, might 16 be the quickest. 17 But in this case, Dr. Jarvis and his 18 colleagues did an epidemiological investigation to look 19 at an apparently unusual infection rate -- knee and -- 20 knee joint infection rates in a couple of hospitals in 21 Atlanta. 22 And one of the factors they looked at was the 23 ASA status of the patients. And they concluded that 24 having an ASA class equal to or greater than 3 was 25 itself an independent risk factor statistically --</p>	<p>1 was associated in a statistically significant way with 2 an increased risk of deep joint infection. 3 And, again, you can read that part if -- if 4 you want. But my point -- my -- my question is -- is 5 really -- it's not fair. I'll give you a chance to 6 read it. 7 (Witness reviewing document.) 8 THE WITNESS: So if I can comment. I 9 mean, just to read one sentence. (Reading): 10 "Logistic regression analyses 11 identified being a patient operated on by 12 surgeon X with an ASA class great than 3 13 as the only significant independent risk 14 factor for total knee 15 arthroplasty-associated surgical wound 16 infections are equals." 17 So it was actually the combination of the 18 surgeon and ASA class greater than 3 that operated 19 together. In other words, there was a synergism 20 in here which is shown in Table 4, in fact. So 21 they don't find an independent effect of ASA 22 Class 3. It's a combination of surgeon and ASA 23 class. 24 BY MR. GORDON: 25 Q And -- and thank you for educating me on that.</p>

<p style="text-align: center;">Page 236</p> <p>1 So in this -- and -- and I understand you just 2 briefly skimmed it, but you -- but the -- 3 After doing their -- their various analyses, 4 they concluded that the -- what distinguished one group 5 of patients from another was having Dr. X as their 6 surgeon and an ASA score of 3 or greater, is that 7 right, though that combination of factors increased 8 their -- significantly increased their risk of deep 9 joint infection?</p> <p>10 A At least as described in this particular 11 outbreak, yes.</p> <p>12 Q Right.</p> <p>13 Now, there's no way that they would have been 14 able to make that conclusion if they hadn't looked at 15 surgeon-specific factors or ASA scores; right?</p> <p>16 A Well, for the purposes of this particular 17 investigation, yes.</p> <p>18 Q In other words, if -- if they had come in and 19 they had -- and there's a list of all the things 20 they -- they looked at. It starts on -- the second 21 page, bottom paragraph, on the right hand, medical 22 records and the study of patients reviewed. It lists a 23 whole bunch of different things they -- they looked at.</p> <p>24 Do you see that?</p> <p>25 A Yes, I do.</p>	<p style="text-align: center;">Page 237</p> <p>1 Q Okay. If they had only looked at everything 2 in that list except segregating out the procedures by 3 surgeon and the ASA scores, based on the analysis 4 that -- that I understand you only had a brief chance 5 to review, they wouldn't have been able to conclude 6 that there was any -- any significant risk factor going 7 on that would allow them to make -- to distinguish 8 why -- why one person would get a deep joint infection 9 and one -- and another wouldn't?</p> <p>10 MS. CONLIN: I'm going to object. I 11 think it's kind of unfair. He hasn't had a chance 12 to read this whole study. In the interest of 13 time, I think he's trying to move along. But if 14 you want to ask him specifics, you've got to give 15 him an opportunity to read it, Mr. Gordon.</p> <p>16 MR. GORDON: That's fair.</p> <p>17 Q And, Doctor -- Doctor, if you do want to read 18 it, that's fine. I think -- I think my question is -- 19 is a little bit more general and -- but, please, if 20 you -- if you feel otherwise, take the time.</p> <p>21 They concluded it was the combination of a 22 particular surgeon and -- and the surgeon's ASA scores.</p> <p>23 There's no way they could have drawn that 24 conclusion if they hadn't gotten -- gathered the data 25 on the different surgeons and the -- and the different</p>
<p style="text-align: center;">Page 238</p> <p>1 ASA scores and then incorporated that into their 2 analysis; right?</p> <p>3 MS. CONLIN: The same objection.</p> <p>4 THE WITNESS: Well, just looking at the 5 paper rather cursorily, of course, I mean, it's 6 a -- essentially an investigation of a cluster of 7 infections at a particular -- at two hospitals 8 that experienced a sharp increase.</p> <p>9 I'm just reading the first paragraph of 10 the methods. And so it's an effort to understand 11 what was driving essentially an outbreak of -- of 12 infections at these two institutions.</p> <p>13 So they were focusing on trying to 14 understand what -- what factors, whether patient 15 physician or otherwise, might have driven a 16 particular cluster of infections as described 17 here.</p> <p>18 BY MR. GORDON:</p> <p>19 Q And just -- as, I mean, just a general 20 proposition, if you don't look at patient-specific 21 factors and you don't look at surgeon-specific factors, 22 you can't determine whether patient- and/or 23 surgeon-specific factors are playing a role in 24 infection rates; right?</p> <p>25 MS. CONLIN: Objection as to form.</p>	<p style="text-align: center;">Page 239</p> <p>1 THE WITNESS: Well, again, I would 2 actually say that this paper is not about 3 infection rates. This is about the individual 4 determinates of -- of risks.</p> <p>5 The individual was -- the -- the 6 individual infection case was defined as any 7 patient that had a surgical wound infection after 8 total knee arthroplasty.</p> <p>9 So, again, this was not about what was 10 driving the rates but what was driving the risk 11 for specific individuals.</p> <p>12 BY MR. GORDON:</p> <p>13 Q Well, let's go back to your Exhibit 21 and see 14 if I'm being obtuse.</p> <p>15 In -- on the second page of the paper -- or 16 the commentary, you say -- and this is at the bottom of 17 this middle column under confounding. You say 18 (reading):</p> <p>19 "Epidemiologists are well aware of 20 the potential for confounding, to 21 introduce noncausal associations, and 22 generally take steps in the design and 23 analyses" -- "analysis phases of research 24 to address confounding."</p> <p>25 A I'm sorry. Could you --</p>

<p style="text-align: center;">Page 240</p> <p>1 Q It's under confounding in the middle -- in the 2 page -- the -- 3 MS. CONLIN: 18 -- 4 (Witness turning to page.) 5 THE WITNESS: Oh, I see it. Okay. 6 BY MR. GORDON: 7 Q Internal page 1810. 8 A Okay. 9 Q I'll read it again. (Reading): 10 "Epidemiologists are well aware of 11 the potential for confounding, to 12 introduce noncausal associations, and 13 generally take steps in the design and 14 analysis phases of research to address 15 confounding." 16 Right? 17 A Yes. 18 Q And you still agree with that; right? 19 A Yes. 20 Q Okay. If you'll now turn to page -- internal 21 page 1812. 22 (Witness turning to page.) 23 BY MR. GORDON: 24 Q The bottom of the very last paragraph there in 25 the conclusion section, you say -- you and your</p>	<p style="text-align: center;">Page 241</p> <p>1 colleagues say (reading): 2 "It is the responsibility of 3 epidemiologists to design and conduct 4 studies in a way that makes them capable 5 of assisting public health and clinical 6 decisions. We also believe that an 7 evaluation of epidemiologic findings 8 based on a balanced weighing of 9 potentials for false-positive and 10 false-negative biases along with other 11 considerations of strengths and 12 weaknesses within the framework of all 13 other pertinent scientific evidence can 14 and does produce valid scientific 15 knowledge essential to public health 16 actions and to advancement of science." 17 You still agree with that, don't you? 18 A I'm just finding it. Yes, I do. 19 MS. CONLIN: It's on -- 20 THE WITNESS: Confounding. Okay. 21 BY MR. GORDON: 22 Q And -- and here you're talking about public 23 health actions and -- and the advancement of science. 24 Would -- would you agree that this statement 25 as a general proposition is -- is applicable for</p>
<p style="text-align: center;">Page 242</p> <p>1 offering expert testimony in -- in court cases as well? 2 A I think it's a valid statement of 3 interpretation of epidemiological evaluation of 4 epidemiological evidence. 5 Q Okay. And -- and I don't want to focus 6 specifically on -- on the -- Dr. Jarvis's study in 7 Exhibit 22. 8 But just generally when it comes to doing 9 the -- conducting studies and evaluating studies if 10 you're doing an epidemiological study, one of the ways 11 an epidemiologist tries to do it right, do it in the 12 scientifically appropriate way is to consider potential 13 confounders and design the -- the study to, you know, 14 allow for analysis of the impact, if any, of potential 15 confounders; right? 16 A Well, I wouldn't -- I would not describe the 17 full approach of confounding as simplistically as you 18 did. There's consideration on the design side, 19 consideration on the analysis side, and there's also 20 judgment and interpretation of -- of the potential for 21 confounding to lead to an association. 22 Q But starting point for -- for considerations 23 is that you have to actually consider something; right? 24 A (No audible response.) 25 Q Whether something is or is not a potential</p>	<p style="text-align: center;">Page 243</p> <p>1 confounder or could be a potential confounder, you have 2 to consider it at some point along in -- in the process 3 in order to -- to make that determination; right? 4 A Well, at -- you know, again, at -- at the 5 point of interpreting McGovern, specifically I was not 6 involved in the design or analysis and left with 7 interpreting the published manuscript and other 8 related materials that I've seen. 9 Q Well, based on you -- what is published in the 10 paper in addition to the discussions of the antibiotics 11 and the thromboprophylaxis, which we spent some time on 12 in your last deposition, is there anything in there 13 that indicates that they -- they gave any consideration 14 to surgeon-specific factors? 15 A Again, I -- as I -- as I said, I think the 16 strength of the design is the fact that the time 17 period between the Bair Hugger and Hot Dog intervals 18 is rather brief. So I'm not sure what 19 surgeon-specific factors might have changed. 20 And, again, in my expert report, I allude to 21 the strength of the estimate and the potential for 22 confounding to be so strong as to generate an 23 association of an odds ratio of 3.8. 24 Q And when we went through the analysis the last 25 time -- and, again, I don't want to spend a lot of time</p>

Page 244

1 on this, but I want to -- want you to recall the
 2 discussion of Professor Holford's calculation of the
 3 odds ratio based on Dr. Reed's testimony that there
 4 should have been one additional deep joint infection in
 5 each of the cohorts that were considered and
 6 Dr. Holford's calculation came up with an odds ratio of
 7 2.86.

8 Do you recall that?

9 A I recall that, yes.

10 Q And I read your deposition again last night,
 11 and I'm pretty sure that -- what your answer is, but
 12 I -- it was -- it was -- there's just enough of a
 13 question in my mind that I want to ask.

14 Do you have any reason to quarrel with
 15 Dr. Holford's analysis of that 2.86 odds -- odds ratio?

16 A Well, I think it's a straight -- the
 17 calculation of the odds ratio itself is a rather
 18 straightforward matter, I think.

19 The basis for Dr. Reed's comment that the
 20 data set might have this error in it, I'm not sure.
 21 I'm a little bit -- I don't know the basis for that
 22 comment.

23 But the computation of adding one to each of
 24 the appropriate cells is a rather simplistic matter.

25 Q Well, do you have any basis for questioning

Page 245

1 Dr. Reed's testimony that there should have been one
 2 additional infection added to --

3 A Well --

4 Q -- each cohort?

5 A Of course I -- I don't. I simply don't know
 6 what the basis for his suggestion is.

7 Q Okay. Do you need the -- the basis to factor
 8 in his sworn testimony on that point into arriving at
 9 your opinions?

10 A Well, I will only give a more general
 11 response. That when one suggests that there's an
 12 error in the database, it's usually with some specific
 13 justification that a correction is made.

14 Q All right. And the reason I'm asking you this
 15 is because you -- you once again mentioned a 3.8 odds
 16 ratio and -- and you discussed that earlier in your
 17 deposition.

18 Based on Dr. Reed's testimony and
 19 Dr. Holford's recalculation, the odds ratio at most
 20 is -- was 2.86; correct?

21 MS. CONLIN: I'm going to object --

22 THE WITNESS: Yeah.

23 MS. CONLIN: -- to the form of the
 24 question.

25 THE WITNESS: If that's the specific

Page 246

1 number. I'd have to go look to verify that it's
 2 2.86. But it's around -- it's around that value.

3 BY MR. GORDON:

4 Q All right. So in -- in holding the opinions
 5 that you hold today and are prepared to offer in court,
 6 is your opinion based on your assumption that the
 7 McGovern study stands for the proposition that -- that
 8 there is a 3.86 odds -- odds ratio or something else?

9 A Well, the -- relying on the published peer
 10 reviewed paper, the odds ratio that stands in the
 11 literature is 3.8.

12 Q And my question, though, is, Is that what
 13 you're relying on in the opinions you hold as you sit
 14 here today?

15 A Well, as stated in my expert report, I
 16 addressed the issue of the potential for confounding
 17 to lead to an estimate of 3.8.

18 Again, I think if -- if one were to say could
 19 the estimate be 2.8 based on Reed's comment, I think
 20 the same issue still stands around the potential for
 21 confounding to generate a relative risk that is
 22 roughly triple the -- I'm sorry. Yeah -- tripling the
 23 risk for deep joint infection.

24 Q So whether it's 2.8 or 3.8, it doesn't in any
 25 way impact your opinions?

Page 247

1 A You know, again, the point is that you have
 2 to postulate a set of uncontrolled confounding factors
 3 that could lead to such strong association.

4 Q Okay. And just looking at Exhibit 22, one --
 5 there was a -- a -- at least a statistically
 6 significant association with a particular surgeon and a
 7 particular -- and a particular cohort of patients,
 8 their -- their ASA class; right?

9 A Well, the paper shows a particular positive
 10 interaction between being -- having higher ASA class
 11 and having been operated on by a particular surgeon,
 12 yes.

13 Q And neither the surgeon-specific factors or
 14 patient-specific factors were -- were considered in the
 15 McGovern paper; correct?

16 MS. CONLIN: Asked and answered.

17 THE WITNESS: Well, again, I -- I think I
 18 commented. The same institution in a very short
 19 temporal separation of the two time periods.

20 BY MR. GORDON:

21 Q Let's go to the Augustine paper, if you would.
 22 Was that Exhibit --

23 MS. CONLIN: 20.

24 BY MR. GORDON:

25 Q 20. And your -- based on what Dr. Augustine

<p style="text-align: center;">Page 248</p> <p>1 stated in that published paper, would you agree that 2 his protocol called for basing his analysis on one year 3 of hip and knee deep joint infection data when Bair -- 4 when forced-air warming was used at each -- at each 5 institution, a sixty-day wash-out period when they 6 switched from forced-air warming to conductive 7 blankets, and then between six and twenty-four months 8 of -- of conductive blanket deep joint infection data 9 within the institution?</p> <p>10 A That would seem to be what the second 11 paragraph of the materials and methods says.</p> <p>12 Q Okay. So -- and I want to break that down. 13 So the -- the first part of that protocol as 14 you understood it when you read the paper was that 15 whatever the data were by looking at each of these 16 institutions, the -- the data should be one year of 17 Bair Hugger forced-air warming, sixty days where there 18 was a crossover and data was not collected, and then 19 whatever the next six to twenty-four months were of 20 conductive blanket blankets in that particular 21 population; right? That's -- that's 1?</p> <p>22 A That's correct.</p> <p>23 Q Okay. And the second -- a second part of the 24 protocol as you understood it was they were to look at 25 both knee and hip deep joint infection data; right?</p>	<p style="text-align: center;">Page 249</p> <p>1 A It's my understanding, yes. 2 Q Now, when -- let's take a look at the second 3 page of the Augustine paper. 4 (Witness turning to page.)</p> <p>5 BY MR. GORDON:</p> <p>6 Q And under Center 1, it lists conductive fabric 7 and forced-air and number developing infections and 8 number not developing infections, right, in Table 1?</p> <p>9 A Yes.</p> <p>10 Q Okay. So just -- I want to look at the 11 numbers slightly differently than they're presented in 12 this -- in this -- in this table. 13 Would you agree that the -- these data would 14 indicate that there were -- during the conductive 15 fabric period there were two infections in a total of 16 677 procedures?</p> <p>17 A Correct.</p> <p>18 Q And there were six -- 19 And during the forced-air period, there were 20 six infections in a total of 388; is that correct?</p> <p>21 A Yes.</p> <p>22 Q And your understanding based on the protocol 23 is what that is saying is that these data would 24 indicate that there was -- there were 388 knee and hip 25 procedures in the forced-air warming year of which six</p>
<p style="text-align: center;">Page 250</p> <p>1 resulted in -- in deep joint infections; right? 2 A Yes. 3 Q A two-month wash-out period when the data were 4 not collected. 5 And that the 677 procedures of conductive 6 blanket or conductive fabric, that took place -- those 7 took place sixty days after switching from the 8 forced-air warming to the conductive blanket? 9 A You mean -- you mean the data acquisition 10 period? 11 Q Yes. 12 A Yes. 13 Q Okay. And just to be clear. Your 14 understanding was that those 677 procedures included 15 hips and knees? 16 A Let me just verify that on the -- 17 (Witness reviewing document.) 18 THE WITNESS: I'm looking because they 19 are using the term "periprosthetic joint 20 infection." It talks about the McGovern study of 21 hips and knees, but I'm actually looking at the -- 22 the first sentence of the protocol, it says 23 (reading): 24 "Periprosthetic joint infection 25 rates."</p>	<p style="text-align: center;">Page 251</p> <p>1 Just looking for a place where it might 2 specifically say hips and knees. It seems 3 implicit since it's in reference to -- 4 Well, I guess the first sentence of the 5 discussion. (Reading): 6 "This is a multicenter observation of 7 outcome study investigating the possible 8 relationship between FAW and PJI in hip 9 and knee total joint replacement." 10 So that would seem to be where he 11 specified what the outcome is rather than in the 12 method study. Okay. 13 BY MR. GORDON: 14 Q But at least when you -- you read it the first 15 time and then reviewed it again in -- in between our 16 last meeting and today, you understood that these -- 17 these data were based on both hip and knee and the -- 18 the data collection periods that we discussed; right? 19 A Correct. 20 MR. GORDON: Let me show you Exhibit 23. 21 This is a single page bearing Bates 22 Number RMC000025. I will represent to you that 23 this is a document produced in discovery in this 24 litigation by -- pursuant to subpoena to Ridgeview 25 Medical Center.</p>

Page 252	Page 253
1 (The aforementioned document was marked 2 Exhibit 23 for identification by the 3 reporter.) 4 BY MR. GORDON: 5 Q And the first question I'll ask is, Have you 6 ever seen this before? 7 A I don't think I have, no. 8 Q Okay. And if you'll look at the first slide 9 there, it says (reading): 10 "Conductive fabric warming data site 11 reduction in joint implant infections..." 12 It discusses what Ridgeview Medical 13 Center is. Then what I want to direct you 14 attention to are -- are numbers. The first bullet 15 point there, it says (reading): 16 "The total knee arthroplasty 17 infection rate in 2006, 1.55 percent. 18 Warming standard forced-air, 388 cases." 19 Did I read that correctly? 20 A Yes. 21 Q And then the next bullet point there, it says 22 (reading): 23 "Total knee arthroplasty infection 24 rate 2008 to 2009, 0.29 percent. Warming 25 standard conductive fabric, 677 cases."	1 Did I read that correctly? 2 A Yes. 3 Q Okay. And if you read the text below, it says 4 (reading): 5 "Here we have anecdotal evidence of 6 reduced orthopedic knee implant 7 infections. It's from the main hospital, 8 the regional healthcare network in 9 Minnesota, that has switched to air-free 10 conductive fabric warming for the last 11 three years." 12 I'm going to skip a little bit down. 13 Well -- (reading): 14 "Though not using laminar flow, this 15 hospital is known for its high quality 16 and is doing many things to reduce 17 surgical infection as evidenced in its 18 Number 1 ranking overall care among 19 Minnesota hospitals by MyHealthcare -- 20 MyHealthcare.com research. 21 "Nonetheless, it is interesting to 22 note that when they were using forced-air 23 warming, their total knee arthroplasty 24 infection rate was 1.55 percent. When 25 they transitioned to conductive fabric
Page 254	Page 255
1 warming three years ago, their infection 2 rate dropped to 0.29 percent for 2008 to 3 2009. 4 "I recognize that this is anecdotal 5 and does not constitute scientific proof 6 of a linkage between waste heat and wound 7 infection, but it is interesting. 8 "Anytime infection rates drop by over 9 80 percent, it should get your attention. 10 And a 0.8 infection rate is world class 11 by any standard." 12 Did I read that correctly? 13 A Yes. 14 Q Would you agree with me that what this is 15 describing is, first of all, just knee infections? 16 MS. CONLIN: Objection; lack of 17 foundation. 18 THE WITNESS: Well, what it makes 19 reference to in what appears to be a slide is 20 total knee arthroplasty infection rate. 21 BY MR. GORDON: 22 Q There -- is there anything in here that would 23 suggest to you that the infection rates that are -- 24 that are being referenced here are -- include the deep 25 joint infections for hip arthroplasty?	1 MS. CONLIN: The same objection. 2 THE WITNESS: No. The page you provided 3 refers to the total knee arthroplasty. 4 BY MR. GORDON: 5 Q All right. And you would agree that the -- 6 the number for 2006 that's listed here, 388, that's 7 exactly the number in the Augustine paper for Center 8 Number 1 for the forced-air period in Table 1, right, 9 388 cases? 10 A Well, both numbers are 388. 11 Q Okay. And the same thing with the conductive 12 fabric for 2008, 2009, the total number of cases listed 13 is 677. 14 That's the total number of cases in Table 1 15 for Center 1; correct? 16 A Both tables are 677. 17 MR. GORDON: I'll show you what's been 18 marked as Exhibit 24 -- wait. I'm sorry. It's 19 the wrong -- I give you the wrong one. No. No. 20 I gave you the right one. I grabbed the wrong one 21 for Jan. Let me find it. 22 What's -- what's -- there was another 23 exhibit number. 24 MS. CONLIN: 55 -- 35. Augustine 35. 25 MR. GORDON: August 35. I know I had

<p style="text-align: center;">Page 256</p> <p>1 three copies of that.</p> <p>2 You know what, Doctor, I'm going to --</p> <p>3 let me withdraw that because I don't -- I don't</p> <p>4 want to take the time to find it. I know I have</p> <p>5 three copies.</p> <p>6 But I'm going to mark a different exhibit</p> <p>7 as Exhibit 24. Coincidentally, it was previously</p> <p>8 marked as McGovern 24. And this is a document</p> <p>9 bearing Albrecht 0002079 through -2086.</p> <p>10 (The aforementioned document was marked</p> <p>11 Exhibit 24 for identification by the</p> <p>12 reporter.)</p> <p>13 BY MR. GORDON:</p> <p>14 Q I will represent to you that this document was</p> <p>15 produced by Mark Albrecht pursuant to a subpoena in</p> <p>16 this litigation.</p> <p>17 I'm assuming you have not had an opportunity</p> <p>18 to see this before.</p> <p>19 A No, I have not.</p> <p>20 Q And --</p> <p>21 MS. CONLIN: No. He -- this is -- he's</p> <p>22 got a list in --</p> <p>23 MR. GORDON: I'm sorry. Jan is -- I -- I</p> <p>24 didn't mean --</p> <p>25 Q This was a McGovern exhibit, and you --</p>	<p style="text-align: center;">Page 257</p> <p>1 A Oh, I see.</p> <p>2 Q That was one of the -- one of the exhibits you</p> <p>3 would have --</p> <p>4 A Okay.</p> <p>5 Q -- had available to you; right?</p> <p>6 A Okay.</p> <p>7 Q And I --</p> <p>8 A Right. Too many things to remember.</p> <p>9 Q Sure. And I apologize.</p> <p>10 If you'll turn to page 3 of Exhibit 24 and</p> <p>11 look at that Table 1 --</p> <p>12 (Witness turning to page.)</p> <p>13 BY MR. GORDON:</p> <p>14 Q -- and compare it to Table 1 in the Augustine</p> <p>15 paper for Center 1.</p> <p>16 Would you agree with me that those numbers are</p> <p>17 identical?</p> <p>18 A Yes, they are.</p> <p>19 Q Okay. Now I want you to turn back to -- to</p> <p>20 the second page of -- of Samet Exhibit 24, which is</p> <p>21 actually the first cover page of this draft article.</p> <p>22 A I'm sorry. Which page?</p> <p>23 MS. CONLIN: Bates 2080.</p> <p>24 THE WITNESS: I got that. But the first</p> <p>25 page.</p>
<p style="text-align: center;">Page 258</p> <p>1 BY MR. GORDON:</p> <p>2 Q Yeah. And I just -- I wanted to direct your</p> <p>3 attention to the -- you know, the -- the top where it</p> <p>4 says (reading):</p> <p>5 "Forced-air warming linked to</p> <p>6 periprosthetic total joint replacement</p> <p>7 infections."</p> <p>8 Do you see that?</p> <p>9 A Yes, I do.</p> <p>10 Q And per the authors of this,</p> <p>11 Scott D. Augustine, M.D., and Paul D McGovern, M.D.</p> <p>12 Do you see that?</p> <p>13 A Yes, I do.</p> <p>14 Q Would it surprise you to learn that</p> <p>15 Dr. Augustine had drafted this without any knowledge of</p> <p>16 Dr. McGovern and then asked him -- and then sent it to</p> <p>17 Dr. McGovern and asked him to agree to be listed as a</p> <p>18 co-author?</p> <p>19 A I really can't comment on that communication.</p> <p>20 I mean, I --</p> <p>21 Q I'm just asking you if -- if you -- I want you</p> <p>22 to assume for the sake -- for the sake of my question</p> <p>23 that that is the case.</p> <p>24 Would that surprise you? Would that seem to</p> <p>25 you --</p>	<p style="text-align: center;">Page 259</p> <p>1 A Yeah. Under the hypothetical assumption that</p> <p>2 McGovern had not been involved in the preparation of</p> <p>3 the --</p> <p>4 Q I'm -- let me be very specific. For the</p> <p>5 purpose of my question, I would like you to assume that</p> <p>6 Dr. McGovern knew absolutely nothing about this, that</p> <p>7 Dr. Augustine drafted this with the statistical</p> <p>8 analysis done by Mr. Albrecht, and that then only after</p> <p>9 it was drafted Dr. McGovern -- or -- excuse me --</p> <p>10 Dr. Augustine sent a copy to Dr. McGovern and asked him</p> <p>11 if he would like to have his name on this paper. For</p> <p>12 the purpose of my question, please assume those facts.</p> <p>13 Would that surprise you?</p> <p>14 A I'm not going on use the word "surprise." It</p> <p>15 would not be the usual way that a co-author is</p> <p>16 involved in a publication.</p> <p>17 Q Okay. Now, let me show you Exhibit 25.</p> <p>18 Single document bearing Bates Number RMC000039. And,</p> <p>19 again, I will represent to you that this was a document</p> <p>20 produced pursuant to a subpoena by Ridgeview Medical</p> <p>21 Center. And the title of this document is</p> <p>22 "RMC Total Joint Infection Rates 2006 Through 2009."</p> <p>23 (The aforementioned document was marked</p> <p>24 Exhibit 25 for identification by the</p> <p>25 reporter.)</p>

1 BY MR. GORDON:

2 Q Do you see that?

3 A Yes, I do.

4 Q Okay. And if you look at 2006 under knee, it
5 shows a rate of 1.55 percent based on six out of 388
6 procedures; is that correct?

7 A That's correct.

8 Q And that's the exact same number that we saw
9 for 2006 in --

10 What did we mark this exhibit as?

11 MS. CONLIN: I think that was 23.

12 MR. GORDON: Exhibit 23?

13 MS. CONLIN: Let me just double-check.

14 MR. GORDON: The PowerPoint slides.

15 MS. CONLIN: Yeah.

16 MR. SACCHET: 23.

17 MS. CONLIN: 23.

18 BY MR. GORDON:

19 Q Would you agree that the number for 2006 for
20 knees as reflected on Exhibit 25 is the same number
21 that we see on Exhibit 23 for 2006?

22 A Sorry. Just --

23 Q It's that one (indicating).

24 A Yes.

25 Q Okay. It's also the same number that we see

1 on Table 1 for the forced-air period in the Augustine
2 paper; correct?

3 A That's correct.

4 Q Okay. And if you go back to Exhibit 25, the
5 total number of knee procedures for 2008 and 2009 is
6 777, right, on Exhibit 25? Excuse me. 677.

7 A I'm sorry. Which number, again, are you --

8 Q If you combine the number of cases in 2008 and
9 2009 for knees on Exhibit 25, the total is 677; right?

10 A Correct.

11 Q And there were two infections in that -- in
12 those two years of those 677 knee cases; right?

13 A In -- yes, in Exhibit 25.

14 Q On Exhibit 25.

15 And if you do the math, two divided by 677,
16 that would come out to 0.29; right?

17 A I haven't done the math. But that figure is
18 repeated over and over again, so I'll accept it.

19 Q It's the same -- and so the number -- again,
20 the numbers we see on -- for knees on Exhibit 25 for
21 2008 and 2009, they correspond exactly to what's shown
22 in Exhibit 23 for knees for 2008, 2009; correct?

23 A Correct.

24 Q And they correspond exactly to the numbers
25 listed in the Augustine paper for the conductive fabric

1 period for Center 1; right?

2 A Correct.

3 Q But there are no years given in the Augustine
4 paper; right?

5 A That's correct.

6 Q So reading this -- reading the Augustine paper
7 and based on his protocol of one year of forced-air,
8 sixty days wash-out, and then the -- the period of
9 conductive fabric, the -- your understanding when you
10 read this was for Center 1, the data represented an
11 infection rate of 1.5 percent for hip and knee
12 infections over one year, and sixty days after the
13 transition from forced-air to conductive fabric, there
14 were two hip and knee infections out of a total of 677
15 procedures; right?

16 A Right. Again, I -- I commented on what's in
17 the materials, the methods where it says
18 periprosthetic joint infection is specified, and then
19 commented on what was said at the start. But
20 certainly that would lead the reader to view -- to
21 consider that the paper refers to hip and knee.

22 Q Right.

23 A And a continuous period of data collection
24 with the exception of that sixty-day wash-out period;
25 right?

1 A Correct.

2 Q There's nothing in the paper, the published
3 Augustine paper, to indicate that there was a one-year
4 gap in the data for Center 1; right?

5 A Correct.

6 Q Now, if you'll look at Exhibit 25.
7 (Witness turning to exhibit.)

8 BY MR. GORDON:

9 Q You see that for the year 2007 under knees
10 alone there were 344 procedures and no infections;
11 correct?

12 A I'm sorry. 2007, the 344 cases, zero
13 infections.

14 Q And I will -- if -- if -- for purposes of my
15 question I'd like you to assume that Ridgeview
16 continued to use the Bair Hugger in its procedures in
17 2007. For purposes of my question assume that to be
18 the case.

19 Would you agree that if you -- if you followed
20 the protocol that that Dr. Augustine used in his paper
21 of one-year followed by sixty-day wash-out period
22 during the transition and then the data collection for
23 whatever period of time, six to twenty-four months, of
24 conductive fabric, that the -- the data that he would
25 have had to have used if he was just using knees would

Page 264

1 have been 0 percent infections for the forced-air
 2 warming period versus .29 percent during the conductive
 3 fabric period?

4 MS. CONLIN: Objection as to form.

5 THE WITNESS: So I don't know whether
 6 2007 was a -- was -- was used that year under --

7 BY MR. GORDON:

8 Q I understand that. I'm asking you to assume
 9 that.

10 A -- under your proposed assumption that
 11 forced-air warming was used. According to his
 12 protocol of how the time series was devised, it would
 13 have been the forced-air warming year of the
 14 transition and then the further data collection under
 15 with conductive warming.

16 Q And just for -- for purposes of this, I just
 17 want you to focus on the knees on Exhibit 25.

18 You would agree that if -- if the Augustine
 19 protocol was followed just looking at knees, and if
 20 I'm -- if -- I want you to assume that the Bair Hugger
 21 was used throughout 2007 -- then the data would have
 22 been reported as 0 percent infection for forced-air
 23 versus the .29 for knees -- for conductive?

24 MS. CONLIN: Objection as to form, it
 25 assumes facts not in evidence.

Page 265

1 THE WITNESS: Again, only under that --
 2 under that hypothetical assumption if this
 3 protocol were -- your forced-air warming followed
 4 by the transition period followed by conductive
 5 warming, the 2007 would have been the comparison
 6 year.

7 BY MR. GORDON:

8 Q Okay. Now, again, assuming -- I want you to
 9 assume for purposes of my question that they used the
 10 Bair Hugger in 2006 and 2007.

11 If we looked only at hips, would you agree
 12 that the overall infection rate for hips actually went
 13 up when they switched from forced-air warming to
 14 conductive fabric?

15 MS. CONLIN: The same objection. It
 16 assumes facts not in evidence.

17 THE WITNESS: I -- I mean, again, under
 18 the assumption, which I have no information about
 19 as to when forced-air warming was used, .67 and
 20 1.04 corresponding to 2006 and 2007 are numbers
 21 that are lower than 1.1 and 1.33 corresponding to
 22 2008 and '9.

23 BY MR. GORDON:

24 Q So those -- the numbers actually would have
 25 gone up. I'm not -- I'm not suggesting the statistic

Page 266

1 was given, just the raw numbers actually went up for
 2 hips alone when they were switching from Bair Hugger to
 3 conductive fabric?

4 A Well, the example speaks for itself.

5 MS. CONLIN: Yeah.

6 BY MR. GORDON:

7 Q And, in fact, if you look at the combined
 8 numbers of knee and hip, would you agree that if you
 9 used Dr. Augustine's protocol of one year -- the -- the
 10 final year of forced-air warming, sixty-day wash-out,
 11 and then whatever period -- additional period of
 12 conductive fabric, and was -- again, my -- for the
 13 purposes of my question assuming that this was -- that
 14 Ridgeview continued to use the Bair Hugger in 2006 to
 15 2007, the one-year fabric -- excuse me -- the one-year
 16 Bair Hugger period would have had an combined infection
 17 rate of .37 based on Exhibit 25; right?

18 A Apparently.

19 MS. CONLIN: The same objection.

20 THE WITNESS: I mean, I haven't checked
 21 the math, but the figure listed here is
 22 .37 percent.

23 BY MR. GORDON:

24 Q And based on this, that number would go up in
 25 the first conductive -- excuse me. Yeah -- in the

Page 267

1 first conductive fabric year of 2008, it would go up
 2 from .37 to .76; right?

3 A Well, the figure for 2008, as you say, is
 4 .76, yes.

5 Q And 2009 would go down to .41; right?

6 A That's the figure for 2009.

7 Q And I don't want to have to spend a lot of
 8 time doing deep math here.

9 But would you agree with me that if you looked
 10 at 2007, the combined rates, and compared it --
 11 compared it to a combined rate of 2008 and 2009, the
 12 absolute raw numbers would not show a decrease in
 13 infections as between the Bair Hugger and the
 14 conductive fabric? Is that right?

15 A I think the question is if you compare the
 16 combined rate for 2007 with what the combined rate
 17 would have -- would be for 2008 and 2009, the figure
 18 for 2007 would be lower.

19 Q And I'm not suggesting again statistically
 20 stating.

21 But just as an absolute number, it would be
 22 slightly lower; right?

23 A The percentage would be lower, yes.

24 Q And, again, if Augustine was following his
 25 purported protocol in this publication, then the

Page 268

1 Center 1 using both hip and knee and using his protocol
 2 would have -- not only would not have shown an
 3 improvement in joint infection rates by switching to
 4 conductive fabric, it would have shown a slight
 5 detriment; right?

6 MS. CONLIN: The same objection.

7 THE WITNESS: I mean, again, under the
 8 assumptions that 2007 was the forced --
 9 appropriate forced-air warming year. According to
 10 the protocol, the findings would be different
 11 using 2007 compared to 2006, if -- that's I think
 12 the question.

13 BY MR. GORDON:

14 Q Was there anything in his protocol that would
 15 suggest that it would be appropriate under any
 16 circumstances to skip a -- to just skip over a year?

17 A I don't have the protocol in front of me.
 18 This -- if, in fact, this relates to -- what is in
 19 Exhibit 25 relates to the results provided in the
 20 published paper for Center 1 and the numbers aligned.
 21 But the years aren't given. The center description is
 22 simply -- simply Center Number 1. I -- the -- the --
 23 omission of 2007, if indeed it were a forced-air
 24 wanting year, it would not correspond to what's stated
 25 in the published papers.

Page 269

1 Q So if these numbers on Exhibit 25 from
 2 Ridgeview Medical Center accurately reflect what was
 3 happening at Ridgeway Medical Center and if Center 1 in
 4 Augustine papers -- Augustine's paper is, in fact,
 5 Ridgeview Medical Center, would you agree with me that
 6 Dr. Augustine's paper did not follow his own protocol?
 7 Let's start with that question.

8 A Well, if -- I mean, with -- with the two
 9 assumptions as to the nature of Center 1, its
 10 connection to Ridgeview and so on, and with the
 11 assumption the 2007 was a forced-air warming year,
 12 then the numbers provided in Table 1 of Exhibit 20
 13 would appear to deviate from the protocol as stated in
 14 the materials and -- and methods.

15 Q And I'm not going to ask you to do complicated
 16 calculations right now, but if -- if you can tell me
 17 just by eyeballing it.

18 If you were to substitute the numbers from
 19 Exhibit 25 for combined joint infection rates for '07
 20 versus '08 and '09 for Center 1, would that have do you
 21 think an impact on the multicenter pooled results?

22 A I'm sorry. What am I substituting?

23 Q If I -- if instead of the numbers that
 24 Dr. Augustine used for Center 1 you substituted the
 25 combined numbers shown on Exhibit 25 and used 2007 as

Page 270

1 the Bair Hugger year in 2008 and '9 as the conductive
 2 fabric year -- year or period, would that have any
 3 impact on the multicenter pooled results?

4 A Well, if, just to be clear, point -- the .37
 5 figure were used, if I -- if I understand correctly, I
 6 mean, the -- the estimate would be lower. I mean,
 7 the -- the direction in which the multicenter pulled
 8 us, it would be pulled -- it would be downward.

9 Q And, again, I know it would probably take a --
 10 take some time to do an analysis.

11 But when you say downward, you mean it
 12 would -- it would tend to show that the impact of
 13 changing from forced-air warming to conductive fabric
 14 had less of an association with the decrease in
 15 surgical site --

16 A Yes, the infection --

17 Q -- infections?

18 A The first mode would be reduced.

19 Q Can you tell if it would be reduced to a point
 20 where it would no longer be statistically significant?

21 A I can't make that calculation.

22 Q Okay. Understood.

23 And so for purposes of my question, I'd like
 24 you to assume that Center 1 as reflected in
 25 Dr. Augustine's paper is Ridgeview Medical Center. I

Page 271

1 would also like you to -- to assume that the data set
 2 forth in Exhibit 25 accurately reflects the infection
 3 rates for Ridgeway Medical Center during the periods
 4 reflected. And I'd also like you to assume that if
 5 Dr. Augustine's protocol -- well, strike that. I would
 6 also like you to assume that Bair Hugger was used at
 7 Ridgeview Medical Center in both 2006 and 2007. And,
 8 finally, the data that Dr. Augustine used in his paper
 9 for Center 1 covered 2006 through 2009 omitting 2000 --
 10 the data from 2007.

11 If all those things are in fact true, would
 12 you agree with me that the conclusions of
 13 Dr. Augustine's published paper would not be something
 14 that will support your opinions?

15 MS. CONLIN: Objection --

16 THE WITNESS: Oh.

17 MS. CONLIN: -- as to form. And I think
 18 as stated previously as the court went in the
 19 report, in the Augustine paper.

20 Subject to that, you may answer.

21 THE WITNESS: Okay. I mean, again, I
 22 understand why you're offering the assumptions.
 23 And I think I answered the question.

24 The -- under those assumptions, the
 25 estimate for Center 1 would not be 4.59 but some

1 other figure much lower, and it would have some
2 effect on the pooled estimate.

3 And -- and beyond that, I can't say how
4 it would influence my overall judgment of the
5 paper. But I think if one were to do the
6 calculations, Center Number 2 would stand with its
7 very strong risk, Center Number 3 has a relatively
8 low risk, and the evidence from this paper would
9 be less convincing than it is in its published
10 form.

11 BY MR. GORDON:

12 Q Okay. How many cases are listed for Center 2
13 in total?

14 A Center 2, a total of four cases.

15 Q I mean, the four infections -- the total --
16 the total end would be 218 plus 171 plus 4; is that
17 right?

18 A 218 plus 171 plus 4.

19 Q And that would be 393; is that right?

20 A Correct.

21 Q Now, the total number of cases for -- listed
22 on Exhibit 1 for -- or Table 1 for forced-air would
23 be -- in the multicenter pooled results would be 929
24 plus 16; right?

25 A I'm sorry. Can you say that again.

1 Q If you add the total number of infections and
2 the total number not developing infections for the
3 multicenter pooled results for forced-air, that would
4 be 16 plus 929 or 944; right?

5 MS. CONLIN: 945.

6 THE WITNESS: 945.

7 BY MR. GORDON:

8 Q 945.

9 Is that right?

10 A 16 plus 929 is 945.

11 Q Okay. Now, if you go back to Center 1, the
12 total number of forced-air cases listed is 388; right?

13 A Correct.

14 Q If you look at Exhibit 25, if you used the
15 combined hip and knee and the total number for 2007,
16 that would be 537; correct?

17 A Correct.

18 Q So that would add 155 cases to the total
19 number of forced-air cases; right?

20 A I'm sorry. Say your -- give me your math
21 again. Why don't we just accept that your --

22 Q Well, my point is simply that Center 1 if -- I
23 want you to assume that as reported by Dr. Augustine
24 he's only reporting hip -- he's only -- excuse me --
25 he's only reporting knee infections without saying so.

1 Okay?

2 And if you used the combined numbers aside
3 from the difference in infection rates, the absolute
4 total number attributable to Center 1 goes up; right?

5 A It is combined infection rates.

6 Q And without -- I understand without doing
7 the -- the numbers, you can't give -- give an exact
8 number.

9 But you agree that the -- the overall
10 percentage rate of combined infection rates at
11 Ridgeview from the 2007 period versus 2008, 2009 the --
12 the actual number actually goes slightly up; right?

13 A I'm sorry. I think I lost you on that one.

14 MS. CONLIN: I am too.

15 BY MR. GORDON:

16 Q Okay. Again, the -- the combined number for
17 2007 at Ridgeview was .37. And if you add 2008 and
18 2009 for the combined number -- we haven't done the
19 math, but we -- we --

20 You agree that it's going to be something a
21 little bit higher than .37; right?

22 MS. CONLIN: Objection; form.

23 THE WITNESS: It will be higher then if
24 you average .4 for 1 point, yes, clearly it would
25 be higher.

1 BY MR. GORDON:

2 Q And in the paper, Dr. Augustine reports that
3 the difference in Center 1 that -- that forced-air
4 warming is not only not a little bit lower than
5 conductive fabric, but it's 4.59 times as high; right?

6 A Well, the odds ratio is 4.5 million.

7 Q And if you take that out and add all the, you
8 know, numbers in, is it -- do you have -- are you able
9 to tell me whether the difference you see in the
10 393 cases reported for Center 2 would result in there
11 being a statistically significant odds ratio for the
12 multicenter pooled results?

13 MS. CONLIN: Objection; asked and
14 answered.

15 THE WITNESS: I'm not sure I can answer
16 the question as you asked it. I think I commented
17 before that -- again, that substituting the
18 combined data for what is in the table would lead
19 to a reduction in the odds ratio for Center 1, and
20 that would correspondingly reduce any pool in the
21 three studies.

22 BY MR. GORDON:

23 Q And given the relative size of the -- of
24 the -- of Center 1 and Center 2, would you agree that
25 having Center 1 change from having a 4.59 odds ratio to

Page 276

1 a -- an odds ratio of slightly under 1.0, the overall
 2 impact on the multicenter pooled result would be to --
 3 to render any apparent difference between forced-air
 4 warming and conductive fabric not statistically
 5 significant?

6 MS. CONLIN: Objection as to form, asked
 7 and answered.

8 THE WITNESS: Yeah. Again, I haven't
 9 done the calculations. Clearly the sample size
 10 using the combined hip and knee for Center 1 is
 11 much larger than that of Center 2, and there would
 12 be a substantial impact on the pooled estimate.

13 BY MR. GORDON:

14 Q And several times in your -- in the July
 15 deposition and again today you -- you referenced the
 16 Augustine paper as something that provides further
 17 support for the -- the findings in the McGovern paper;
 18 right?

19 A Yes, I have.

20 Q Okay. If you assume everything I've asked you
 21 to assume about the Ridgeview data on Exhibit 25 and --
 22 and what Center 1 actually is, would -- would you still
 23 think that the Augustine paper provides support for the
 24 conclusions in the McGovern paper?

25 A Oh, it -- probably state that it would raise

Page 277

1 uncertainty about the -- the results as reported in
 2 the Augustine paper.

3 Q And you would agree that a peer reviewer only
 4 gets to review what is presented to him or her; right?

5 A A peer reviewer typically sees what is in the
 6 publication and any supplemental materials, correct.

7 Q And, again, assuming that my -- what I -- all
 8 the facts that I've asked you to assume are correct,
 9 no -- a peer reviewer wouldn't have had any way of
 10 knowing that the numbers that Dr. Automatic reported in
 11 his paper are inaccurate, would he or she?

12 MS. CONLIN: It assumes facts not in
 13 evidence.

14 You may answer.

15 THE WITNESS: I mean, a peer reviewer
 16 would not have access. Assuming that Exhibit 25
 17 is relevant to the Augustine paper, would not have
 18 access to this information.

19 BY MR. GORDON:

20 Q Now, if you had been asked to be a peer
 21 reviewer for the Augustine paper and presented with the
 22 paper as drafted, as published but were also provided
 23 with the information that I've just gone through with
 24 you and the assumptions that I've asked you to make,
 25 would you, as a peer reviewer, say, "Eh, no problem.

Page 278

1 Let the paper go in as" -- "as drafted"?

2 A Well, I think if I received a paper to peer
 3 review with additional material questioning the data,
 4 I would simply refer the matter back to the editor.

5 Q Wouldn't -- Doctor, wouldn't you agree that if
 6 my assumptions are accurate, that this Augustine paper
 7 is misleading?

8 A I -- again, as I -- as I said, if the
 9 assumptions with regard to Center 1 as presented, as
 10 represented is true, it certainly raises questions
 11 about the findings as provided in the published paper.

12 Q And my -- my question is predicated on the
 13 assumption. If I'm all wrong, then obviously what you
 14 answer to this hypothetical is -- is of no import.

15 But if I'm correct, if -- if the assumptions
 16 that I've asked you to make prove to be substantiated
 17 by the evidence, would you agree that what
 18 Dr. Augustine wrote is misleading?

19 A Again, as I said, if the assumptions are
 20 correct, it would raise a great deal of uncertainty
 21 about the findings as presented here because they
 22 would not be based on the whole data set or perhaps
 23 according to the protocol of the correct data set.

24 Q Whether -- whether it would be misleading or
 25 not, you can't say?

Page 279

1 A Well, the findings would be different from
 2 what is in the report.

3 Q And the report is -- reports a 78 percent
 4 reduction in implant infections; right?

5 A That's correct.

6 Q And you -- you previously testified that
 7 you -- based on that 3.8 odds ratio, that that
 8 translates to about a 74 percent reduction in
 9 infections; is that right?

10 A I haven't done the calculations. But, yes,
 11 approximately.

12 Q Well, it's essentially --

13 A Yeah.

14 Q -- the same thing as -- as attributable risk,
 15 isn't it?

16 A Yes.

17 Q So whatever you said the attributable risks
 18 was in the report.

19 78 and 74 are pretty close to each other;
 20 right?

21 A They are.

22 Q So if the Augustine paper used -- used the
 23 data as I'm suggesting -- no. I --

24 For purposes of my question, I want you to
 25 assume than instead of using the combined data from

Page 280

1 Ridgeview and do -- and following the protocol by using
 2 2007 and comparing it to 2008 and 2009, Dr. Augustine
 3 picked out the data only for knees, used 2006, ignored
 4 2007, and then used 2008 and '9, and entered those into
 5 the -- the calculus for the multicenter pooled results.

6 Would you agree with me that that would be
 7 a -- an improper methodological approach to presenting
 8 data?

9 MS. CONLIN: The same objection.

10 THE WITNESS: Well, again, under the
 11 assumptions you've given, it would suggest that he
 12 did not follow his protocol as described, albeit
 13 briefly, in the materials and methods.

14 BY MR. GORDON:

15 Q And throughout your career, you've been
 16 troubled by the misuse of data and science by the
 17 tobacco industry, haven't you?

18 A At times, yes.

19 Q Yeah.

20 Well, have there any times you've been -- you
 21 haven't been troubled by the misuse --

22 A Well --

23 Q -- of the science by the tobacco --

24 A -- I -- I think perhaps I was referring to
 25 science in those matters and the like, yes.

Page 280

Page 281

1 Q Any day with a y in it, basically; right?
 2 If -- if what I'm telling you is true, if
 3 the -- if the evidence I'm providing you is true that
 4 the -- the owner of the company that is competing, is
 5 trying to sell a competitive product to forced-air
 6 warming is using data in the way I've -- I've described
 7 it to you, does -- does that give you any kind of
 8 similar concerns about the way -- similar to the way
 9 the tobacco industry manipulated and misused data?

10 A Well, I -- I would simply say that, you know,
 11 under the assumptions that you have listed, again if
 12 Augustine deviated from the protocol and perhaps to
 13 have a high odds ratio in the Center Number 1, that
 14 would certainly represent a deviation from appropriate
 15 scientific practice.

16 Q Would that bother you?

17 A If that were the case, it would bother me,
 18 yes.

19 MR. GORDON: Could we take a quick break?

20 THE WITNESS: Yeah. Absolutely. So why
 21 don't we -- how --

22 THE VIDEOGRAPHER: The time is 9:58 a.m.
 23 We are off the record.

24 (A brief recess was taken.)

25 THE VIDEOGRAPHER: We are back on the

Page 282

Page 283

1 record. The time is 10:07 a.m.

2 BY MR. GORDON:

3 Q Dr. Samet, if you were to disregard the
 4 McGovern -- the observational component of the McGovern
 5 paper and disregard the Augustine paper, just assume
 6 for the purposes of my question those two things either
 7 did not exist or you concluded for whatever reason that
 8 they're just -- they're just not reliable, would you
 9 still be of the opinion that the Bair Hugger is a
 10 substantial contributing cause to deep joint
 11 infections?

12 A Well, I mean, I think in my expert report, I
 13 lay out the mechanistic basis for the plausibility of
 14 the association that is observed in -- particularly in
 15 the McGovern paper at the time of my expert report.

16 The McGovern paper supplies the only estimate
 17 of the risk associated for deep joint infection
 18 associated with use of the forced-air warming Bair
 19 Hugger device. So absent the quantitative estimate
 20 from that paper, it would be -- while there would be a
 21 quite plausible mechanistic basis for increased risk,
 22 there would not have been asked an association in -- in the
 23 real world.

24 Q So without McGovern and without the -- excuse
 25 me. I want to be clear. I'm not talking about the

1 bubble component of McGovern. I'm talking about only
 2 the observational component and now the Augustine.

3 Without those two things, would you agree that
 4 you could -- would no longer be in a position to opine
 5 that the Bair Hugger was a substantial contributing
 6 cause -- factor causing joint infections?

7 A Well, again, the basis on which the --
 8 (Mr. Boone joins the deposition
 9 proceeding.)

10 THE WITNESS: -- magnitude of the
 11 association was considered in my report comes from
 12 the McGovern estimate. And absent that estimate,
 13 I would not have another way to construct a
 14 quantitative estimate.

15 BY MR. GORDON:

16 Q And without a way to construct a quantitative
 17 estimate, you couldn't say whether something was or was
 18 not a substantial contributing cause; right?

19 A I would not be able to judge the quantitative
 20 magnitude of the association.

21 Q In fact, based on the -- what you describe as
 22 the mechanistic basis -- information -- mechanistic
 23 data, all that does is -- is lead to a possibility, not
 24 a probability; right?

25 A Well, again, I think -- I wouldn't use the

Page 284

1 word "possibility." "Probability." Those
 2 considerations which I addressed extensively in my
 3 expert report related to the biological plausibility
 4 and the coherence of the total body of evidence.

5 Q And my -- and that's -- again, assume --
 6 disregard the -- the observational component of
 7 McGovern, disregard Augustine. All you have are those
 8 mechanistic data or studies.

9 Would you be -- would you be offering the
 10 opinion as an epidemiologist to a reasonable degree of
 11 medical certainty that the Bair Hugger is a substantial
 12 contributing cause to joint infections?

13 A To restate what I think I said is, I would
 14 have no basis for describing the quantitative
 15 magnitude of the risk which underlies the -- the use
 16 of the word "substantial" as we discussed previously.

17 Q So you wouldn't be offering that -- that
 18 opinion; correct?

19 A I wouldn't have the basis for doing so.

20 Q Okay. Let's talk about the mechanistic
 21 component that you have discussed.

22 What -- what -- you know, sort of a
 23 50,000-foot view. What -- what are you -- what are you
 24 describing as -- as the mechanistic evidence?

25 A Well, I think it's laid out in my expert

Page 285

1 report, and I think there's a figure that describes
 2 that -- the conceptualization of the mechanisms. And
 3 there's a fair amount of text about how the components
 4 of that figure are supported.

5 And I also used the sufficient cause model to
 6 describe how the Bair Hugger device configured into --
 7 essentially creating an additional cause of -- of deep
 8 joint infection, adding to those that already -- that
 9 exist absent Bair Hugger.

10 Q All right. Are -- are you talking about the
 11 figures on page 8 of your report?

12 MS. CONLIN: It's right here
 13 (indicating).

14 THE WITNESS: That's a sufficient cause
 15 piece of -- of it. And then there's the
 16 additional figure which is on page 14.

17 BY MR. GORDON:

18 Q All right. I just want to ask a quick
 19 question or two about Figure 2B on page 8. Then --
 20 then we'll go to the other one.

21 There you -- you have three different pie
 22 charts; right?

23 A In 2B, correct.

24 Q And then you have Cause 1 and Cause 2 and
 25 Cause 3; right?

Page 286

1 A They're so labeled.

2 Q Why is surgery part of the pie in a Cause 2
 3 but not in Cause 3?

4 A Well, these are, again, hypothetical examples
 5 and simply to show that -- that the use of Bair Hugger
 6 creates additional cause. It could be that surgery
 7 could be included there.

8 Again, as I state clearly in the text that
 9 this is a hypothetical and simply intended to show how
 10 the Bair Hugger could lead to the introduction of a
 11 causal mechanism that is otherwise not present. It
 12 couldn't -- again, this was simply a hypothetical.

13 Q Okay. Well, now let's turn to page 14 in your
 14 Figure 3. And you have two arrows coming off of the
 15 Bair Hugger device, one being to disturb unidirectional
 16 flow and other one being microbial contamination of the
 17 surgical field; correct?

18 A Right.

19 Q And between those, you have arrows going
 20 either way.

21 What -- what does that mean?

22 A Well, it's -- it -- it is intended to show
 23 that the -- there's this interaction, if you will,
 24 between the two, that the Bair Hugger device is
 25 elevating the numbers of microbes through introduction

Page 287

1 of organisms, that the device itself is heat, the flow
 2 of air disrupts unidirectional flow. And those two
 3 together lead to this increased dose and increased
 4 number of infectious organisms reaching the surgical
 5 site.

6 Q Okay. So regardless of whether it's through
 7 the mechanism of disturbing unidirectional flow or
 8 microbial contamination of the surgical field or an
 9 interaction between those two factors, the ultimate
 10 mech- -- mechanistic way that you're -- you're positing
 11 that the Bair Hugger would cause the joint infections
 12 would be through an increased dose of infectious
 13 organisms; right?

14 A Well, the path to increased risk would be
 15 through an increased dose, correct.

16 Q And by increased dose of infectious organisms,
 17 you're talking about viable pathogenic bacteria; right?

18 A An increased number of colony-forming
 19 organisms, yes.

20 Q So for shorthand, let's call them CFUs. All
 21 right?

22 A Okay.

23 Q So if what -- through whatever mechanism the
 24 Bair Hugger increases CFUs, that's what your positing
 25 as the mechanistic part of your opinion; right?

<p style="text-align: right;">Page 288</p> <p>1 A I'm suggesting that the pathway -- and I 2 think it's laid out with the arrows from Bair 3 Hugger -- to increased risk is mediated through an 4 increased number of infectious organisms reaching the 5 surgical site.</p> <p>6 Q To conclude that the Bair Hugger is capable of 7 increasing the dose of infectious organisms, you need 8 some evidence that it actually increases the number of 9 CFUs arriving at the surgical site, right, wouldn't 10 you?</p> <p>11 A Well, I think I -- again, it's laid out in my 12 report how the literature supports both -- both 13 pieces, the disturbance of unidirectional flow, 14 increased numbers of infectious organisms in -- in the 15 air.</p> <p>16 And then, of course, there is this -- and 17 also there's demonstration of increased numbers of 18 particles, again a surrogate for what is in the air 19 reaching the surgical site.</p> <p>20 I think there's substantial evidence that's 21 supporting each of the pieces of the diagram.</p> <p>22 Q Okay. Is there any evidence that supports the 23 actual increase in the dose of infectious organisms?</p> <p>24 A I'm not sure what -- what constitutes such 25 evidence. Again, I'd lay out how the pieces of this</p>	<p style="text-align: right;">Page 289</p> <p>1 diagram are supported by the evidence reviewed in the 2 report.</p> <p>3 Q Okay. Well, one of the pieces of evidence you 4 reviewed in the report is --</p> <p>5 MR. GORDON: I'm going to show you 6 Exhibit 26. That's the Stocks [phonetic] paper. 7 (The aforementioned document was marked 8 Exhibit 26 for identification by the 9 reporter.)</p> <p>10 BY MR. GORDON:</p> <p>11 Q That was something you specifically reviewed 12 and cited; correct?</p> <p>13 A Yes, I did.</p> <p>14 MS. CONLIN: What number is this?</p> <p>15 MR. GORDON: I think it's 26.</p> <p>16 MS. CONLIN: Okay.</p> <p>17 BY MR. GORDON:</p> <p>18 Q And in -- you cite the -- Exhibit 26 for the 19 proposition that particles are a valid surrogate for 20 CFUs; right?</p> <p>21 A It's one of the papers I cited, yes.</p> <p>22 Q How did -- how did --</p> <p>23 The researchers in Exhibit 26, how did they 24 conclude that particles were a valid surrogate for 25 CFUs?</p>
<p style="text-align: right;">Page 290</p> <p>1 A Well, they models outcomes relative to CFUs 2 in relationship to particle counts.</p> <p>3 Q How did they go about modeling the CFUs?</p> <p>4 A They used a regression model.</p> <p>5 Q Well, they just make up numbers or --</p> <p>6 A I'm sorry. What -- what is the question?</p> <p>7 Q Well, they measured CFUs, didn't they? They 8 weren't just going into a computer and typing out 9 random numbers?</p> <p>10 A Is the question, What is the underlying data 11 set?</p> <p>12 Q Yeah.</p> <p>13 They -- they -- they measured colony-forming 14 units; correct?</p> <p>15 A In this paper, they measured particles and 16 colony-forming units, correct.</p> <p>17 Q And they did an analysis to see how the -- the 18 number of particles that they measured compared to the 19 number of viable bacteria that they were able to 20 culture out through different active and passive 21 measuring techniques; correct?</p> <p>22 A It's -- I think you more or less described 23 what the protocol was.</p> <p>24 Q So they -- but in order to even come to this 25 conclusion, they actually set up something to measure</p>	<p style="text-align: right;">Page 291</p> <p>1 particles -- measure CFUs; right?</p> <p>2 A Well, they were interested in looking at what 3 predicted the biolog- -- the bacterial population 4 reaching the surgical sites.</p> <p>5 Q Do you recall what the size particles were 6 that correlated in the Stocks paper, Exhibit 26, with 7 the CFUs?</p> <p>8 A The fraction that was statistically 9 significant in models was the 10-micron or greater.</p> <p>10 Q And the studies that you were referring to 11 earlier that you say demonstrate that Bair Hugger 12 increases a number of particles, what size particles 13 does -- has the Bair Hugger been shown to increase?</p> <p>14 A Well, let me --</p> <p>15 I'm sorry. Could you restate the question.</p> <p>16 Q What size particles, in -- in your 17 understanding of the literature upon which you're 18 relying, has the Bair -- does the Bair Hugger cause an 19 increase?</p> <p>20 A Well, I am not sure. I would have to go back 21 and it look at the literature. So sitting here today, 22 I'm not sure how many studies have actually done size 23 fractionated -- aerodynamic size fractionated 24 measures.</p> <p>25 They have measured bacteria at surgical</p>

<p style="text-align: right;">Page 292</p> <p>1 sites. They have measured particles in the air. I'm 2 not sure how many of those studies have done a -- if 3 any have done this kind of size cuts that are shown 4 here.</p> <p>5 Q You -- you said they measure bacteria at 6 surgical sites.</p> <p>7 What -- what studies are you talking about?</p> <p>8 A I'd have to go back to my report and look at 9 them.</p> <p>10 Q Is it your recollection that there were 11 studies that showed that the Bair Huggers significantly 12 increased bacteria at surgical sites?</p> <p>13 A I need a moment to look through the report. 14 Excuse me. I'm looking through and refamiliarizing 15 myself on what is here.</p> <p>16 (Witness reviewing document.)</p> <p>17 THE WITNESS: I think if the question was 18 did I cite, as I look at it, studies specifically 19 on Bair Hugger and organisms reaching the 20 surgical -- the surgical site, there were studies 21 on contamination in the air but not at surgical 22 sites specifically.</p> <p>23 Q When you say "contamination," you're talking 24 about bacterial contamination?</p> <p>25 A I'm talking about bacterial culture, that's</p>	<p style="text-align: right;">Page 293</p> <p>1 correct.</p> <p>2 Q What studies are those?</p> <p>3 A Again, I need a minute to come back and find 4 those.</p> <p>5 (Witness reviewing document.)</p> <p>6 THE WITNESS: Again, there's a -- one of 7 the studies where the cut -- the counts go up. I 8 just -- sorry. I can't find it right now.</p> <p>9 BY MR. GORDON:</p> <p>10 Q Your -- but your recollection of the study is 11 it actually found a statistically significant increase 12 in bacteria in the air when the Bair Hugger was --</p> <p>13 A Yes.</p> <p>14 Q -- turned on?</p> <p>15 A I -- it was a study of a forced-air warming 16 device. I'm sorry. I just can't --</p> <p>17 Q Well, just -- I know you're on very limited 18 time, so I'm going to just kind of follow through 19 with --</p> <p>20 A Okay.</p> <p>21 Q -- some other things.</p> <p>22 MR. GORDON: Let me show you Exhibit 27. (The aforementioned document was marked 23 Exhibit 27 for identification by the 24 reporter.)</p>
<p style="text-align: right;">Page 294</p> <p>1 BY MR. GORDON:</p> <p>2 Q This is a paper by Christina, et al., in 2012. 3 This was listed in Exhibit C as part of 4 your reference materials; correct?</p> <p>5 MS. CONLIN: Is this Exhibit 27?</p> <p>6 MR. GORDON: Correct.</p> <p>7 THE WITNESS: That's correct. It's 8 listed.</p> <p>9 BY MR. GORDON:</p> <p>10 Q And we -- we -- would you agree with me that 11 this Christina paper, Exhibit 27, actually comes to a 12 different conclusion than the Stocks paper that you 13 actually cite in -- in the text of your opinion? In 14 other words, the Christina, et al., study concluded 15 that there was not a correlation between particles and 16 bacteria in operating theaters for arthroplasty?</p> <p>17 A Just give me a moment --</p> <p>18 Q Sure.</p> <p>19 A -- to look at it.</p> <p>20 (Witness reviewing document.)</p> <p>21 THE WITNESS: The only -- I'm going to -- 22 this is a rather sparse presentation. There are 23 two points. It says the size cuts are not the 24 same as the Stocks article. They are greater than 25 .5 and greater than 5.</p>	<p style="text-align: right;">Page 295</p> <p>1 The data are described only as not 2 revealing any statistically significant 3 correlation. So I don't know what the actual 4 values of correlation were, so...</p> <p>5 But from what they describe, they did not 6 find a significant correlation with the .5 and the 7 greater than 5-micron cuts.</p> <p>8 BY MR. GORDON:</p> <p>9 Q Why was it that you chose to sort of 10 specifically reference and discuss the Stocks paper in 11 your expert opinion, but you didn't say anything about 12 the Christina paper?</p> <p>13 MS. CONLIN: You mean other than listing 14 it as a reference review?</p> <p>15 MR. GORDON: Right.</p> <p>16 THE WITNESS: I don't have a particular 17 recollection. I reviewed a great deal of 18 material.</p> <p>19 I also mentioned the Darius [phonetic] 20 paper with regard to ventilation, CFUs, and 21 infection rates.</p> <p>22 BY MR. GORDON:</p> <p>23 Q Well, both the Darius paper and the Stocks 24 paper in your view support the notion that if the Bair 25 Hugger increases particulate counts, that that is an</p>

<p style="text-align: center;">Page 296</p> <p>1 indication it was -- would likely be increasing 2 bacterial counts; right?</p> <p>3 A Well, the general point was that -- that the 4 particle count is a surrogate for -- a useless 5 surrogate indicator of -- I think the presence of the 6 level of CFUs in the air, correct.</p> <p>7 Q And -- and the Christina paper that you had 8 available to you and that you reviewed, that actually 9 was contrary to that conclusion; right?</p> <p>10 A Well, it's contrary. It's also very 11 uninformative as to actually what was found and what 12 the data are. There's simply -- there's no 13 quantitative information given as to the correlation. 14 It's simply dismissed as not statistically 15 significant.</p> <p>16 Q Okay. And -- and -- but you didn't say 17 anything about this contrary study; right?</p> <p>18 A It's not directly mentioned in my expert 19 report or cited.</p> <p>20 MR. GORDON: Let me show you Exhibit 28. 21 This is a paper by Landrin, et al., from 2005. 22 (The aforementioned document was marked 23 Exhibit 28 for identification by the 24 reporter.)</p> <p>25 ///</p>	<p style="text-align: center;">Page 297</p> <p>1 BY MR. GORDON: 2 Q This was not something you reviewed; is that 3 correct?</p> <p>4 MS. CONLIN: Are you representing that 5 it's not on this list?</p> <p>6 MR. GORDON: I don't believe it is, 7 but...</p> <p>8 THE WITNESS: That's not on the list.</p> <p>9 BY MR. GORDON: 10 Q And given that it's not on your list, we can 11 conclude that it was something that you did not review; 12 right?</p> <p>13 A I don't think I've seen this paper.</p> <p>14 Q Did you do any search on your own to find 15 literature that would have cast a different light on 16 the question of whether particles are a valid surrogate 17 for bacterial colony-forming units?</p> <p>18 A Well, I think if you look in my expert 19 report, I describe the searches that were undertaken.</p> <p>20 Q But -- and does -- can we conclude that search 21 either didn't --</p> <p>22 Well, can we conclude that that search did not 23 come up with Exhibit 28?</p> <p>24 A Apparent -- apparently not. I mean, you 25 know, again, I will say that searches are of varying</p>
<p style="text-align: center;">Page 298</p> <p>1 sensitivity in finding the full scope of the 2 literature. But the citations that -- I'm sorry. The 3 search strategies that are used are laid out on 4 page 9.</p> <p>5 Q You considered the question of whether 6 particles could be valid surrogates for viable bacteria 7 of colony-forming units to be an important question, 8 didn't you?</p> <p>9 A I considered it to be part of the evidence. 10 Considered -- it's laid out in the mechanistic figure.</p> <p>11 Q Do you -- are -- are you confident that you 12 did a thorough search for published peer reviewed 13 literature that addressed -- that addresses the issue 14 of whether particles can be a valid surrogate for CFUs?</p> <p>15 A I'm not sure what you mean. I mean, I did 16 not carry out a systematic review on the topic, if 17 that's the question.</p> <p>18 Q Okay.</p> <p>19 MR. GORDON: I'm going to show you what's 20 been marked as Exhibit 29. It's a 2017 paper by 21 Oguz, et al.</p> <p>22 (The aforementioned document was marked 23 Exhibit 29 for identification by the 24 reporter.)</p> <p>25 ///</p>	<p style="text-align: center;">Page 299</p> <p>1 BY MR. GORDON: 2 Q And this is not listed on your reference 3 materials; correct?</p> <p>4 A No.</p> <p>5 Q Have you ever seen this paper before today?</p> <p>6 A Not to my knowledge, no.</p> <p>7 Q Were you aware from any source that a study 8 had been conducted that compared bacterial counts at 9 the surgical site when a Bair Hugger was used versus 10 when a Hot Dog was used during actual orthopedic 11 surgeries?</p> <p>12 A Well, again, the only thing that I can say is 13 that the searches were carried out, the search terms 14 as described. This one may have been published 15 sufficiently close to the time the searches were done 16 that it was not picked up.</p> <p>17 Q Okay. Would you agree that an actual study in 18 an OR during actual orthopedic surgeries measuring 19 colony-forming units when the Bair Hugger is on versus 20 when a Hot Dog is on would be a better form of evidence 21 than measuring particles?</p> <p>22 A I'm sorry. Let me look at the paper.</p> <p>23 Q Sure.</p> <p>24 (Witness reviewing document.)</p> <p>25 THE WITNESS: Again, this -- just to</p>

<p style="text-align: center;">Page 300</p> <p>1 comment on the paper, it appears to be a study in 2 which people were assigned to warming with either 3 a Bair Hugger or a Hot Dog device, and 4 measurements were made.</p> <p>5 I -- I think the point I was addressing 6 in my mechanistic formulation that's laid out in 7 the diagram had to do with particles and bac -- 8 bacteria that can cause infection, CFUs.</p> <p>9 This is something -- about something 10 different. And I have not read this before, so I 11 would have to take a closer look at it to 12 understand what -- what they did and what they 13 found.</p> <p>14 BY MR. GORDON:</p> <p>15 Q Fair enough. And, again, in the interest of 16 time, I won't ask you to take the time to look at that 17 since it was something that you've seen before today.</p> <p>18 MR. GORDON: I'm going to show you 19 Exhibit 30, previously marked as McGovern 20 Exhibit 6.</p> <p>21 (The aforementioned document was marked 22 Exhibit 30 for identification by the 23 reporter.)</p> <p>24 BY MR. GORDON:</p> <p>25 Q And because it was a McGovern exhibit, does</p>	<p style="text-align: center;">Page 301</p> <p>1 that mean that you -- this is something you would have 2 read?</p> <p>3 A I may have. I actually really don't remember 4 seeing this, sitting here now.</p> <p>5 Q Okay.</p> <p>6 A Yeah.</p> <p>7 Q And I just direct your conclusions on the 8 front page. It says (reading):</p> <p>9 "Use of forced-air warming devices 10 does not increase the bacterial count in 11 the vicinity of the operative field. 12 However, it is noted that the 13 introduction of airborne particles from 14 outside the laminar flow zones, the 15 operative field increases the bacterial 16 count. Many of those which could be 17 pathogens themselves were sterile -- 18 sterile particles that form an itis for 19 pathogen growth." 20 Do you see that?</p> <p>21 A I see the conclusion section, yes.</p> <p>22 Q Okay. Then if you would turn to -- the pages 23 aren't numbered -- but the one that has a discussion on 24 it. It's about four or five in from the end. 25 (Witness turning to page.)</p>
<p style="text-align: center;">Page 302</p> <p>1 MS. CONLIN: What's the exhibit number on 2 this? 30?</p> <p>3 MR. GORDON: Yes.</p> <p>4 MS. CONLIN: Okay.</p> <p>5 BY MR. GORDON:</p> <p>6 Q Do you have the page that has discussion on 7 it?</p> <p>8 A Yes, I do.</p> <p>9 Q Okay. And the second paragraph there, I'll 10 read it. (Reading):</p> <p>11 "The particle counts measured from 12 the four experiments show that when the 13 surgeon enters the vicinity of the 14 operative field, the particle count rise 15 in that zone. This is most marked when 16 the surgeon touches the disinfected skin. 17 This could represent epithelial particle 18 shedding from the patient.</p> <p>19 "However, there is no suggestion from 20 these results that turning on the FAW 21 device makes any difference to operative 22 field particle counts. Bacterial 23 sampling from operative field and FAWs 24 have shown that there were very low 25 numbers of skin bacteria found within</p>	<p style="text-align: center;">Page 303</p> <p>1 these various areas of the operating 2 theater.</p> <p>3 "These experiments show no notable 4 increase in either ambient particle count 5 or bacterial count in the vicinity of an 6 operative field when a forced-air device 7 is being used. Low bacterial counts in 8 all experiments are reassuring.</p> <p>9 "However, the potential for 10 introduction of airborne particles from 11 outside the laminar flow zones to the 12 operative field is a potential concern. 13 There could be pathogens themselves or 14 sterile particles that form an itis for 15 pathogen growth." 16 Then it goes on to say (reading):</p> <p>17 "Further studies are required to 18 ascertain if there is any relationship 19 between the increase in particle levels 20 seen here and possible increase in 21 pathogens during the operative 22 procedures." 23 Was this information you considered in 24 drawing your conclusions? 25 A I actually -- (coughing) excuse me. I don't</p>

Page 304

1 recall directly considering this. I would have to
 2 relook at it now in terms of a simulation. Clearly
 3 this was a simulation, and I'd have to relook at the
 4 details.

5 Q Would it impact your assessment of this to
 6 know that this study was originally funded by
 7 Augustine?

8 A I don't have a comment on that.

9 Q Would it impact your evaluation of this to
 10 know that -- well, two of the researchers were
 11 Dr. McGovern and Dr. Reed, the same people who were
 12 behind the -- part of the McGovern paper that you --
 13 that we talked about?

14 A Right. My -- my understanding is that they
 15 are both well-respected clinicians. And in the case
 16 of Reed as a researcher later in the field, I don't
 17 have a basis to suspect them from what I had -- the
 18 information I have.

19 Q Would it impact your assessment of this at all
 20 that to know that no effort was ever made to publish
 21 it?

22 A Again, I just can't comment on it. I don't
 23 know its history.

24 MS. CONLIN: Why don't you tell him why,
 25 Mr. Gordon.

Page 305

1 MR. GORDON: Well, we'll let the judge
 2 decide why.

3 Let me show you Exhibit 31, previously
 4 marked as Augustine Exhibit 8.

5 (The aforementioned document was marked
 6 Exhibit 31 for identification by the
 7 reporter.)

8 BY MR. GORDON:

9 Q Have you ever seen this document before?
 10 A This one, no.

11 Q Okay. I will represent to you that this is a
 12 compilation of several experiments performed by
 13 Augustine employees in the 2007, 2008 time frame and
 14 was produced through a subpoena in this litigation to
 15 the Augustine Company.

16 Given all the research activities that
 17 Dr. Augustine and his employees undertook and published
 18 with respect to the Bair Hugger, would it surprise --
 19 does it surprise you that they had on five different
 20 occasions tried different ways to demonstrate that
 21 bacteria was actually coming out of the Bair Hugger and
 22 couldn't find -- and couldn't demonstrate that?

23 MS. CONLIN: Objection; it
 24 mischaracterizes the record.

25 You can answer.

Page 306

1 THE WITNESS: I'm -- I'm not sure I can
 2 answer given that I've been handed a 29-page
 3 document. I don't --

4 BY MR. GORDON:

5 Q Fair enough.

6 A -- know the contents of it.

7 Q And you've never seen it before?

8 A I've never seen it before to be able to
 9 comment.

10 Q And, again, one of the -- one of the areas
 11 that has troubled you as a scientist throughout your
 12 career has been the way that the tobacco industry
 13 suppressed unfavorable research; right?

14 A Well, they -- I'm not sure if it's
 15 suppressed. I mean, I think what its concern is, is
 16 their efforts to discredit evidence and sometimes to
 17 publish, if you will, counterevidence. They -- from
 18 the documents, we know they did not publish much of
 19 their work in peer reviewed literature. That was not
 20 their intent.

21 Q Well, were you -- have you ever -- strike
 22 that.

23 So a criticism of the tobacco industry for
 24 suppressing internal research that was unfavorable to
 25 the tobacco industry, that's not part of your

Page 307

1 criticisms of the tobacco industry; is that right?

2 A I'm not sure what you're getting at. I mean,
 3 I think it's fair to say that all of us who work in
 4 tobacco control understood that the tobacco industry
 5 was carrying out research related to its products that
 6 may have either given insight into why their
 7 cigarettes are so addictive or into their toxicity,
 8 and none of this information was generally published.
 9 They did publish in the peer review literature.

10 But I'm not sure what your question is.

11 I mean, there was, obviously, a concern on
 12 the part of all of us -- all of us without knowledge
 13 until the documents came out that they harbored
 14 secrets, if you will, about the risks of their
 15 products and how they enhanced them to create
 16 addictiveness.

17 Q Does it concern -- would it -- strike that.

18 Would it concern you at all if the evidence
 19 demonstrated that Dr. Augustine and his employees were
 20 engaged in doing all sorts of research about the Bair
 21 Hugger, a competitive product, and published those
 22 results that could be construed as demonstrating that
 23 the Bair Hugger was unsafe but did not publish and kept
 24 secret evidence that the Bair Hugger was safe?

25 MS. CONLIN: Objection; it assumes facts

<p style="text-align: center;">Page 308</p> <p>1 not in evidence, and it mischaracterizes the 2 record.</p> <p>3 You may answer.</p> <p>4 THE WITNESS: I mean, I don't think the 5 only answer -- I mean, I have no knowledge of what 6 Augustine Biomedical or Augustine and his 7 coworkers did or did not -- did or did not do, and 8 so it's -- it's very hard for me to answer the 9 question.</p> <p>10 If the suggestion is that only selective 11 results were published, I would have to know what 12 was published and what was not published.</p> <p>13 BY MR. GORDON:</p> <p>14 Q And for the purposes of my question, I'm just 15 asking you to assume that.</p> <p>16 If it turns out that Augustine and his 17 employees published things that made Bair Hugger look 18 bad and anything that exonerated Bair Hugger was not 19 published, is that something that you would find 20 troubling?</p> <p>21 MS. CONLIN: The same objection. It 22 assumes facts not in evidence.</p> <p>23 THE WITNESS: Again, I think -- if -- if 24 legitimate scientific research being is carried 25 out, the entire body of findings should be</p>	<p style="text-align: center;">Page 309</p> <p>1 published.</p> <p>2 BY MR. GORDON:</p> <p>3 Q So the answer to my question is, if that were 4 to be the case, that would be troublesome to you?</p> <p>5 MS. CONLIN: The same objection.</p> <p>6 THE WITNESS: Again, I said that, you 7 know, open -- science -- scientists publish the 8 full the body of their work.</p> <p>9 MR. GORDON: Let me show you what's been 10 marked as Exhibit 32. It's a document bearing 11 Bates Numbers Augustine 3548 through -3551.</p> <p>12 (The aforementioned document was marked 13 Exhibit 32 for identification by the 14 reporter.)</p> <p>15 BY MR. GORDON:</p> <p>16 Q First of all, Dr. Samet, have you ever seen 17 this before?</p> <p>18 A No.</p> <p>19 Q Were you -- has it ever somehow come to your 20 attention that there was a guide to product liability 21 litigation involving the Bair Hugger?</p> <p>22 A I'm sorry. That such a guide exists?</p> <p>23 Q Yes.</p> <p>24 A I'm not aware of it.</p> <p>25 Q Okay. And you see that this has a --</p>
<p style="text-align: center;">Page 310</p> <p>1 The front page would indicate that it was 2 coming from a group of attorneys; right?</p> <p>3 A Well, it's -- it listed it was coming from 4 Kennedy Hodges, LLP. I have no knowledge of 5 authorship.</p> <p>6 Q And would it surprise you to learn that 7 Dr. Augustine authored it?</p> <p>8 A Again, I have no knowledge of authorship.</p> <p>9 Q I understand you have no knowledge.</p> <p>10 I'm asking you, If you were to find out that 11 Dr. Augustine was behind this litigation guide, would 12 that surprise you?</p> <p>13 MS. CONLIN: Lack of foundation.</p> <p>14 THE WITNESS: I -- I have -- I just 15 simply can't answer the question other than I'm 16 not sure if it surprises me or not. Sure, who 17 typically authorizes such documents or what the 18 purpose is, I just don't have a basis for 19 answering the question to say whether I'd be 20 surprised or not.</p> <p>21 BY MR. GORDON:</p> <p>22 Q If you could turn to page 4 of Exhibit 32. 23 (Witness turning to page.)</p> <p>24 BY MR. GORDON:</p> <p>25 Q And under recent research, do you see that</p>	<p style="text-align: center;">Page 311</p> <p>1 paragraph? The first paragraph there, it says 2 (reading):</p> <p>3 "The most dramatic research directly 4 linking Bair Hugger to periprosthetic 5 joint infections (PJIs) was conducted by 6 McGovern -- McGovern, et al., and 7 published in the November 2011 Journal of 8 Bore -- Journal of Bone & Joint Surgery 9 BR," Britain. "This research" -- "this 10 research shows that Bair Hugger FAW is 11 linked to a 3.8 times increase in deep 12 joint infections."</p> <p>13 Do you see that?</p> <p>14 A Yes, I do.</p> <p>15 Q And that's the same 3.8 figure that you used 16 in your report and forms the basis -- formed the basis 17 of your attributable risk assessment; right?</p> <p>18 A It's the figure given in McGovern.</p> <p>19 Q Now, for purposes of my question, I'd like you 20 to assume that Augustine and his employees were 21 directly involved in the McGovern paper, directly 22 involved in the other papers purporting to show 23 bacterial contamination inside the Bair Hugger or 24 particle distribution or particle increases when the 25 Bair Hugger was turned on, disruption of laminar</p>

Page 312

1 airflow, those mechanistic things, that Dr. Augustine
 2 and his employees also conducted research that
 3 demonstrated that the Bair Hugger didn't actually
 4 increase bacteria at the surgical site and never
 5 published it, and Dr. Augustine hired a group of
 6 plaintiffs' lawyers and drafted this guide to product
 7 liability litigation in their name, set up a website
 8 ostensibly in the name of the plaintiffs' law firm,
 9 sent out the guide to other plaintiffs' law firms in an
 10 effort to encourage litigation.

11 If you -- if all those facts were assumed to
 12 be true, is that something that you, as a professional
 13 scientist, epidemiologist, public health expert -- is
 14 that something that you -- you'd feel comfortable
 15 associating yourself with?

16 MS. CONLIN: I'm going to object to the
 17 form of the question both based on the fact that
 18 it misstates the record and it misstates the facts
 19 and makes assumptions that are not borne out by
 20 the evidence in this case.

21 THE WITNESS: I'm not going to ask you to
 22 repeat the question, but...

23 And, again, I have not seen this
 24 document. I do find it difficult, which I think
 25 you implied, that an entire body of literature in

Page 313

1 this sense has been both created and -- and
 2 legitimate investigators like McGovern and Reed
 3 somehow were contaminated by a single individual.

4 So I -- I think that's the -- the
 5 scenario that you laid out with your list of
 6 assumptions. I really can't comment on it because
 7 I don't have the basis for -- for doing so.

8 But I find it somewhat implausible to
 9 think that, you know, legitimate academics with
 10 strong records would allow their work to be
 11 subverted, if you will.

12 BY MR. GORDON:

13 Q It's happened, though, hasn't it, in the past?
 14 We talked about Dr. Wakefield [phonetic] and all the
 15 other co-authors on his Lancet papers.

16 A I'm not sure that Dr. Wakefield was a
 17 legitimate academic. Unfortunately, his co-authors
 18 signed onto that particular paper.

19 Q By legitimate academics, I was referring to
 20 some of the co-authors of Dr. Wakefield's Lancet paper.

21 A Certainly there were people who had solid
 22 reputations who were co-authors on that paper.

23 MR. GORDON: Let's take a quick break.

24 See if I have --

25 THE VIDEOGRAPHER: The time is 10:53 a.m.

Page 314

1 We are off the record.

2 (A brief recess was taken.)

3 THE VIDEOGRAPHER: We are back on the
 4 record. The time is 10:56 a.m.

5 MR. GORDON: Dr. Samet, I have a number
 6 of other things I can -- can take time asking you
 7 about. But I understand you have a very narrow
 8 time window. So out of respect to you and your
 9 other commitments, I'm going to pass the witness.

10 THE WITNESS: Great. Thank you very
 11 much.

12 MS. CONLIN: Thanks.

13 ***

14 EXAMINATION

15 BY MS. CONLIN:

16 Q So I just have a couple questions, Doctor.

17 You are relying in part of on Dr. Jarvis and
 18 Dr. El-Ghobashy [phonetic]; is that correct?

19 MR. GORDON: Object to the form of the
 20 question.

21 THE WITNESS: Yes.

22 BY MS. CONLIN:

23 Q Okay. And with respect to this issue of
 24 particulates being a proxy for CFUs, were you aware the
 25 PJI consensus in 2016 says that there is a correlation

Page 315

1 between the two?

2 MR. GORDON: Object to the form of the
 3 question.

4 THE WITNESS: Yes, I am aware.

5 BY MS. CONLIN:

6 Q And you're aware that Dr. Jarvis testified to
 7 that as well; correct?

8 MR. GORDON: The same objection.

9 THE WITNESS: Yes, I am.

10 BY MS. CONLIN:

11 Q Okay. One of the studies that you mentioned
 12 in your report, the Moretti [phonetic] study, did that
 13 show direct evidence of significant increase in
 14 bacteria or CF use in the Bair Hugger?

15 MR. GORDON: The same objection.

16 BY MS. CONLIN:

17 Q I believe it's on page 12 --

18 A Let me --

19 Q -- 13 of your report?

20 A Let me find my report. But that rings a
 21 bell, and it's perhaps what I was looking for.

22 I'm sorry. Page --

23 Q I think it's 13, Doctor.

24 (Witness turning to page.)

25 THE WITNESS: That's correct.

Page 316

1 BY MS. CONLIN:

2 Q Okay. And with respect to Exhibits 30 and 31,
 3 Mr. Gordon took you through some documents and asked
 4 you if you had -- knew whether they were published or
 5 not.

6 You reviewed Dr. McGovern's testimony in this
 7 case; correct?

8 A Yes, I did.

9 Q Okay. And do you recall him testifying that
 10 the study wasn't well-conducted not controlled and
 11 flawed --

12 MR. GORDON: Object to the form.

13 BY MS. CONLIN:

14 Q -- or things to that -- and things to that
 15 effect?

16 A I'm --

17 MR. GORDON: Object to the form --

18 THE WITNESS: I'm not sure I --

19 MR. GORDON: -- of the question.

20 THE WITNESS: I'm not sure I remember
 21 that, but I --

22 BY MS. CONLIN:

23 Q Okay.

24 A -- can go back and remind myself.

25 Q Okay. Finally, with respect to -- you

Page 317

1 testified in your first deposition about Dr. Holford's
 2 time trend analysis?

3 A Yes, I did.

4 Q Okay. And you -- you mentioned it was simply
 5 too small to do any sort of formal analysis.

6 What did you mean by that?

7 A I meant a formal time series analysis in
 8 which there was an effort to sort of more specifically
 9 stratify events over time and see what happened. The
 10 data set is too small for that purpose.

11 Q Okay. And with respect to his chart on the
 12 time trend analysis, you understand that he included
 13 data from 2007?

14 A That's right. He included data from 2007
 15 before the surveillance system was fully implemented and
 16 online in July of 2008.

17 Q Okay. And did you take --

18 Do you take issue with that, then?

19 A Well, it --

20 MR. GORDON: Object to the form of the
 21 question.

22 THE WITNESS: Well, it -- it means that
 23 the initial period that's brought into the
 24 averaging is information that is different from
 25 what comes later and probably underestimated.

Page 318

1 BY MS. CONLIN:

2 Q Okay. And would that impact his conclusions
 3 as set forth in his report?

4 A It would affect his conclusions that they
 5 were sort of two humps of infections. The first one
 6 was simply a reflection of the lower period being
 7 averaged in with the full surveillance time period.

8 Q Okay. And Mr. Gordon talked to you about some
 9 of the potential confounders as set forth in the Borak
 10 and Holford reports, including impact of wound
 11 dressings, impact of SSI bundles, and the MSSA
 12 screening.

13 Have you seen any published literature that
 14 would suggest that these are, in fact, true confounders
 15 as it relates to the results in the McGovern study?

16 MR. GORDON: Object to the form of the
 17 question.

18 THE WITNESS: I'm not aware that they
 19 affect deep joint infection rates.

20 MS. CONLIN: Thank you. I have no
 21 further questions.

22 ***

23 FURTHER EXAMINATION

24 BY MR. GORDON:

25 Q Just a quick follow up on Holford. I don't

Page 319

1 have it in front of me.

2 But are -- are you saying that if you were to
 3 disregard the data prior to July 2008, that that would
 4 flatten out the infection rate curve between July 2008
 5 and when -- whenever the end of the Bair Hugger study
 6 period was?

7 A What I'm suggesting is that if prior to
 8 July 2008 when the full surveillance system was
 9 implemented if the averaging started there moving
 10 forward, the estimate would start at a higher --
 11 higher point. And I can't comment on sort of that
 12 dip, as I recall, coming along the middle and then
 13 rising again. The -- the curve would look different.

14 Q Well, specifically with respect to that dip,
 15 is there any reason to think that if you lopped off
 16 that pre-July 2008 data, that that dip would somehow
 17 disappear?

18 A I would have to look at the timing of the --
 19 that dip versus the window. The curve -- the curve
 20 would look different. I can't, sitting here without
 21 that in front of me, comment.

22 MR. GORDON: Thank you. I have nothing
 23 further.

24 MS. CONLIN: I'm done.

25 We'll read and sign.

Page 320

1 THE VIDEOGRAPHER: Okay. This concludes
 2 today's deposition of Dr. Jonathan Samet.
 3 The time is 11:01 a.m. We are off the
 4 record.

5 (The deposition proceedings were
 6 concluded at 11:01 a.m.)

7 -000-

Page 321

1 STATE OF CALIFORNIA)
 2) ss.
 3 COUNTY OF LOS ANGELES)
 4 I, JONATHAN SAMET, M.D., having appeared for my
 5 deposition on August 8, 2017, do this date state that
 6 I have read the foregoing deposition and that I have
 7 made any corrections, additions, or deletions that I
 8 was desirous of making in order to render the within
 9 transcript true and correct.

10 IN WITNESS WHEREOF, I have hereunto subscribed my
 11 name this day of , 2017.

13 JONATHAN SAMET, M.D.

Page 322

1 ERRATA SHEET

2 Case Name:

3 Deposition Date:

4 Deponent:

5 Pg. No. Now Reads Should Read Reason

6 _____
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22 Signature of Deponent

23 SUBSCRIBED AND SWORN BEFORE ME
 24 THIS ____ DAY OF _____, 2017.

25 (Notary Public) MY COMMISSION EXPIRES: _____

Page 323

1 CERTIFICATE OF REPORTER

2 I, DORIEN SAITO, CSR 12568, CLR, a certified
 3 Shorthand reporter in and for the State of
 4 California, County of Los Angeles, do hereby certify;

5 That JONATHAN SAMET, M.D., the witness named
 6 in the foregoing deposition, was, before the
 7 commencement of the deposition, duly administered an
 8 oath in accordance with CCP 2094;

9 That said deposition was taken down in
 10 stenograph writing by me and thereafter transcribed
 11 Into typewriting under my direction.

12 That before completion of the deposition,
 13 review of the transcript [X] was [] was not
 14 requested. If requested any changes made by the
 15 deponent (and provided to the reporter) during the
 16 period allowed are appended hereto.

17 I further certify that I am neither counsel
 18 for nor related to any party to said action, nor in
 19 any way interested in the outcome thereof.

20 Dated this 11th day of August, 2017.

22 CERTIFIED SHORTHAND REPORTER
 23 IN AND FOR THE COUNTY OF
 24 LOS ANGELES, STATE OF CALIFORNIA

A	221:15 243:10 additional (10) 220:6,12 221:12 244:4 245:2 266:11 278:3 285:7,16 286:6 additions (1) 321:7 address (3) 232:10 239:24 240:14 addressed (3) 246:16 284:2 298:13 addresses (1) 298:13 addressing (1) 300:5 administered (2) 219:16 323:7 advancement (2) 241:16,23 aerodynamic (1) 291:23 affect (4) 233:13,13 318:4,19 aforementioned (14) 221:1 222:15 225:21 233:18 252:1 256:10 259:23 289:7 293:23 296:22 298:22 300:21 305:5 309:12 ago (2) 219:23 254:1 agree (30) 228:24 229:12 233:2 240:18 241:17,24 248:1 249:13 254:14 255:5 257:16 258:17 260:19 263:19 264:18 265:11 266:8 267:9 269:5 271:12 274:9,20 275:24 277:3 278:5 278:17 280:6 283:3 294:10 299:17 air (15) 211:4 212:4 215:19 216:6,14 218:8 224:14,15 287:2 288:15,18 292:1,21 293:12 296:6 air-free (1) 253:9 airborne (4)	215:14 216:10 301:13 303:10 airflow (1) 312:1 al (12) 214:24 215:17,21 216:8,12,16 233:16 294:2,14 296:21 298:21 311:6 albeit (1) 280:12 Albrecht (5) 215:8 216:19 256:9 256:15 259:8 aligned (1) 268:20 alignment (2) 231:17 233:10 allow (3) 237:7 242:14 313:10 allowed (1) 323:16 allude (1) 243:20 ambient (1) 303:4 American (1) 214:22 amount (1) 285:3 analyses (3) 235:10 236:3 239:23 analysis (18) 232:24 237:3 238:2 239:23 240:14 242:14,19 243:6,24 244:15 248:2 259:8 270:10 290:17 317:2,5,7,12 and/or (1) 238:22 anecdotal (2) 253:5 254:4 Anesthesia (1) 216:10 Angeles (7) 211:14 212:13 218:1 218:12 321:2 323:4 323:23 answer (13) 214:10 244:11 271:20 275:15 277:14 278:14 305:25 306:2 308:3,5,8 309:3 310:15 answered (4)	247:16 271:23 275:14 276:7 answering (1) 310:19 antibiotics (1) 243:10 Anytime (1) 254:8 apologize (2) 221:19 257:9 apparent (2) 276:3 297:24 apparently (3) 234:19 266:18 297:24 appear (1) 269:13 appeared (1) 321:4 appears (2) 254:19 300:1 appended (1) 323:16 applicable (1) 241:25 applied (1) 228:13 approach (5) 224:22 225:6 229:16 242:17 280:7 approaches (1) 224:4 appropriate (6) 229:14 242:12 244:24 268:9,15 281:14 approximately (2) 218:13 279:11 April (1) 216:18 areas (2) 303:1 306:10 arrive (1) 224:9 arrived (1) 226:25 arriving (2) 245:8 288:9 arrows (3) 286:14,19 288:2 arthroplasty (11) 214:23 215:16,20 239:8 252:16,23 253:23 254:20,25 255:3 294:16 arthroplasty-associ... 235:15 article (2)
a.m (9) 212:14 218:2,14 281:22 282:1 313:25 314:4 320:3 320:6 able (6) 236:14 237:5 275:8 283:19 290:19 306:8 absent (3) 282:19 283:12 285:9 absolute (4) 220:5 267:12,21 274:3 absolutely (2) 259:6 281:20 abstract (1) 234:15 academic (1) 313:17 academics (2) 313:9,19 accept (2) 261:18 273:21 access (2) 277:16,18 accurate (1) 278:6 accurately (2) 269:2 271:2 acquisition (1) 250:9 action (1) 323:18 actions (2) 241:16,23 active (1) 290:20 activities (1) 305:16 actual (6) 274:12 288:23 295:3 299:10,17,18 add (5) 221:21 273:1,18 274:17 275:7 added (1) 245:2 addictive (1) 307:7 addictiveness (1) 307:16 adding (2) 244:23 285:8 addition (2)	221:15 243:10 additional (10) 220:6,12 221:12 244:4 245:2 266:11 278:3 285:7,16 286:6 additions (1) 321:7 address (3) 232:10 239:24 240:14 addressed (3) 246:16 284:2 298:13 addresses (1) 298:13 addressing (1) 300:5 administered (2) 219:16 323:7 advancement (2) 241:16,23 aerodynamic (1) 291:23 affect (4) 233:13,13 318:4,19 aforementioned (14) 221:1 222:15 225:21 233:18 252:1 256:10 259:23 289:7 293:23 296:22 298:22 300:21 305:5 309:12 ago (2) 219:23 254:1 agree (30) 228:24 229:12 233:2 240:18 241:17,24 248:1 249:13 254:14 255:5 257:16 258:17 260:19 263:19 264:18 265:11 266:8 267:9 269:5 271:12 274:9,20 275:24 277:3 278:5 278:17 280:6 283:3 294:10 299:17 air (15) 211:4 212:4 215:19 216:6,14 218:8 224:14,15 287:2 288:15,18 292:1,21 293:12 296:6 air-free (1) 253:9 airborne (4)	215:14 216:10 301:13 303:10 airflow (1) 312:1 al (12) 214:24 215:17,21 216:8,12,16 233:16 294:2,14 296:21 298:21 311:6 albeit (1) 280:12 Albrecht (5) 215:8 216:19 256:9 256:15 259:8 aligned (1) 268:20 alignment (2) 231:17 233:10 allow (3) 237:7 242:14 313:10 allowed (1) 323:16 allude (1) 243:20 ambient (1) 303:4 American (1) 214:22 amount (1) 285:3 analyses (3) 235:10 236:3 239:23 analysis (18) 232:24 237:3 238:2 239:23 240:14 242:14,19 243:6,24 244:15 248:2 259:8 270:10 290:17 317:2,5,7,12 and/or (1) 238:22 anecdotal (2) 253:5 254:4 Anesthesia (1) 216:10 Angeles (7) 211:14 212:13 218:1 218:12 321:2 323:4 323:23 answer (13) 214:10 244:11 271:20 275:15 277:14 278:14 305:25 306:2 308:3,5,8 309:3 310:15 answered (4)	247:16 271:23 275:14 276:7 answering (1) 310:19 antibiotics (1) 243:10 Anytime (1) 254:8 apologize (2) 221:19 257:9 apparent (2) 276:3 297:24 apparently (3) 234:19 266:18 297:24 appear (1) 269:13 appeared (1) 321:4 appears (2) 254:19 300:1 appended (1) 323:16 applicable (1) 241:25 applied (1) 228:13 approach (5) 224:22 225:6 229:16 242:17 280:7 approaches (1) 224:4 appropriate (6) 229:14 242:12 244:24 268:9,15 281:14 approximately (2) 218:13 279:11 April (1) 216:18 areas (2) 303:1 306:10 arrive (1) 224:9 arrived (1) 226:25 arriving (2) 245:8 288:9 arrows (3) 286:14,19 288:2 arthroplasty (11) 214:23 215:16,20 239:8 252:16,23 253:23 254:20,25 255:3 294:16 arthroplasty-associ... 235:15 article (2)

assumption (7) 246:6 259:1 264:10 265:2,18 269:11 278:13 assumptions (13) 268:8 269:9 271:22 271:24 277:24 278:6,9,15,19 280:11 281:11 312:19 313:6	authored (1) 310:7 authorizes (1) 310:17 authors (2) 226:7 258:10 authorship (2) 310:5,8 Automatic (1) 277:10 available (3) 221:8 257:5 296:8 average (1) 274:24 averaged (1) 318:7 averaging (2) 317:24 319:9 aware (10) 231:25 232:8 239:19 240:10 299:7 attributable (5) 230:14 274:4 279:14 279:17 311:17 audible (1) 242:24 August (7) 211:15 212:14 218:1 218:13 255:25 321:5 323:20	211:4 212:4 216:21 218:7 231:5,17 243:17 248:3,17 263:16 264:20 265:10 266:2,14,16 267:13 270:1 271:6 282:9,18 283:5 284:11 285:6,9 286:5,10,15,24 287:11,24 288:2,6 291:11,13,18,18 292:11,19 293:12 295:24 299:9,19 300:3 305:18,21 307:20,23,24 308:17,18 309:21 311:4,10,23,25 312:3 315:14 319:5	balanced (1) 241:8 based (23) 215:14 226:19 227:17 229:22 230:1 237:3 241:8 243:9 244:3 245:18 246:6,19 247:25 249:22 251:17 260:5 262:7 266:17,24 278:22 279:7 283:21 312:17 basically (1) 281:1 basing (1) 248:2 basis (16) 244:19,21,25 245:6,7 282:13,21 283:7,22 284:14,19 304:17 310:18 311:16,16 313:7 Bates (4) 251:21 257:23 259:18 309:11 bearing (4) 251:21 256:9 259:18 309:10 behalf (3) 212:11 218:21,23 believe (4) 228:13 241:6 297:6 315:17 bad (1) 308:18 Bafeda (2) 228:7,8 Bafeda's (1) 228:9 Bair (58)	Britain (1) 311:9 broader (2) 224:13,18 brought (1) 317:23 bubble (1) 283:1 bullet (2) 252:14,21 bunch (1) 236:23 bundles (1) 318:11 BURKE (1) 213:10
C				
C (5) 213:1 220:20 221:7 223:18 294:3 calculation (4) 244:2,6,17 270:21 calculations (4) 269:16 272:6 276:9 279:10 calculus (1) 280:5 California (7) 211:14 212:13 218:1 218:12 321:1 323:4 323:23 call (1) 287:20 called (1) 248:2 capable (2) 241:4 288:6 care (1) 253:18 career (2) 280:15 306:12 carried (2) 299:13 308:24 carry (1) 298:16 carrying (1) 307:5 case (16) 218:10 222:24 224:2 228:15 229:25 233:25 234:17 239:6 258:23 263:18 281:17 304:15 309:4 312:20 316:7 322:2				

cases (16) 242:1 252:18,25 255:9,12,14 261:8 261:12 263:12 272:12,14,21 273:12,18,19 275:10 cast (1) 297:15 causal (2) 224:10 286:11 cause (16) 282:10 283:6,18 284:12 285:5,7,14 285:24,24,25 286:2 286:3,6 287:11 291:18 300:8 causing (1) 283:6 CCP (2) 219:17 323:8 cells (1) 244:24 center (46) 215:6 249:6 251:25 252:13 255:7,15 257:15 259:21 262:1,10 263:4 268:1,20,21,22 269:2,3,3,5,9,20,24 270:24,25 271:3,7,9 271:25 272:6,7,12 272:14 273:11,22 274:4 275:3,10,19 275:24,24,25 276:10,11,22 278:9 281:13 certain (1) 224:3 certainly (6) 226:22 234:14 262:20 278:10 281:14 313:21 certainty (1) 284:11 CERTIFICATE (1) 323:1 certified (2) 323:2,22 certify (2) 323:4,17 CF (1) 315:14 CFUs (15) 287:20,24 288:9 289:20,25 290:1,3,7	291:1,7 295:20 296:6 298:14 300:8 314:24 chance (5) 226:25 227:23 235:5 237:4,11 change (1) 275:25 changed (1) 243:19 changes (3) 232:9 233:12 323:14 changing (1) 270:13 chart (1) 317:11 charts (1) 285:22 checked (1) 266:20 chose (1) 295:9 Christina (5) 294:2,11,14 295:12 296:7 cigarettes (1) 307:7 circumstances (1) 268:16 CIRESI (1) 213:3 citations (1) 298:2 cite (3) 289:18 292:18 294:13 cited (3) 289:12,21 296:19 class (8) 234:24 235:12,18,22 235:23 247:8,10 254:10 clear (4) 222:12 250:13 270:4 282:25 clearly (4) 274:24 276:9 286:8 304:2 clinical (3) 216:9 224:19 241:5 clinicians (1) 304:15 Clinics (1) 215:7 close (4) 231:17 233:9 279:19 299:15	closer (1) 300:11 CLR (3) 211:25 212:15 323:2 cluster (2) 238:6,16 co-author (2) 258:18 259:15 co-authored (1) 226:1 co-authors (5) 226:15 313:15,17,20 313:22 coherence (1) 284:4 cohort (2) 245:4 247:7 cohorts (2) 233:6 244:5 Coincidentally (1) 256:7 colleagues (2) 234:18 241:1 collected (2) 248:18 250:4 collection (4) 251:18 262:23 263:22 264:14 colony-forming (6) 287:18 290:13,16 297:17 298:7 299:19 column (2) 228:17 239:17 combination (4) 235:17,22 236:7 237:21 combine (1) 261:8 combined (17) 266:7,16 267:10,11 267:16,16 269:19 269:25 273:15 274:2,5,10,16,18 275:18 276:10 279:25 come (7) 223:15 236:18 261:16 290:24 293:3 297:23 309:19 comes (4) 242:8 283:11 294:11 317:25 comfortable (1) 312:14 coming (6)	computer (1) 290:8 conceptualization (1) 285:2 concern (5) 303:12 306:15 307:11 307:17,18 concerning (2) 220:3 225:14 concerns (1) 281:8 conclude (6) 237:5 288:6 289:24 297:11,20,22 concluded (7) 227:16 234:23 236:4 237:21 282:7 294:14 320:6 concludes (1) 320:1 conclusion (8) 226:19 236:14 237:24 240:25 290:25 294:12 296:9 301:21 conclusions (8) 224:9 228:14 271:12 276:24 301:7 303:24 318:2,4 conduct (1) 241:3 conducted (4) 232:24 299:8 311:5 312:2 conducting (1) 242:9 conductive (34) 215:5 231:18 248:6,8 248:20 249:6,14 250:5,6,8 252:10,25 253:10,25 255:11 261:25 262:9,13 263:24 264:2,15,23 265:4,14 266:3,12 266:25 267:1,14 268:4 270:1,13 275:5 276:4 confident (1) 298:11 configured (1) 285:6 confounder (2) 243:1,1 confounders (11) 230:18 231:2,3,3,13 231:16 233:7
---	--	---	---

242:13,15 318:9,14	constitutes (1)	278:15,20,23 279:5	cover (1)	276:21 278:3,22,23
confounding (18)	288:24	284:18 285:23	257:21	279:23,25 280:3,8
230:13,15 231:4,7,9	construct (2)	286:17 287:15	covered (2)	280:16 281:6,9
239:17,20,24 240:1	283:13,16	289:12 290:14,16	229:19 271:9	283:23 284:8
240:11,15 241:20	construed (1)	290:21 293:1 294:4	covering (2)	290:10 295:1
242:17,21 243:22	307:22	294:6,7 296:6 297:3	229:9 230:7	296:12 317:10,13
246:16,21 247:2	contaminated (1)	299:3 314:18 315:7	coworkers (1)	317:14 319:3,16
Conlin (68)	313:3	315:25 316:7 321:9	308:7	database (1)
213:3,4 214:5 218:23	contamination (8)	correction (1)	245:12	245:12
218:23 226:2	216:11,15 286:16	245:13	date (2)	321:5 322:3
229:21 230:21	287:8 292:21,23,24	corrections (1)	dated (4)	321:5 322:3
237:10 238:3,25	311:23	321:7	215:9 216:18 217:5	215:9 216:18 217:5
240:3 241:19	contend (1)	correctly (5)	323:20	323:20
245:21,23 247:16	225:11	220:21 252:19 253:1	day (4)	281:1 321:11 322:23
247:23 254:16	contents (1)	254:12 270:5	323:20	323:20
255:1,24 256:21	306:6	correlated (1)	days (4)	248:17 250:7 262:8
257:23 260:11,13	context (1)	291:6	262:12	262:12
260:15,17 264:4,24	224:18	correlation (6)	deal (3)	224:5 278:20 295:17
265:15 266:5,19	continued (5)	294:15 295:3,4,6	decide (1)	305:2
268:6 271:15,17	215:2 216:2 217:2	296:13 314:25	decision (2)	221:9 232:12
273:5 274:14,22	263:16 266:14	correspond (3)	decisions (1)	241:6
275:13 276:6	continuous (1)	261:21,24 268:24	248:18	248:18
277:12 280:9	262:23	corresponding (2)	decrease (2)	267:12 270:14
285:12 289:14,16	contrary (3)	265:20,21	deep (17)	273:3 235:2 236:8
294:5 295:13 297:4	296:9,10,17	correspondingly (1)	237:8 244:4 246:23	237:8 244:4 246:23
302:1,4 304:24	contrast (1)	275:20	cursorily (1)	248:3,8,25 250:1
305:23 307:25	232:25	corroborate (1)	254:24 267:8	254:24 267:8
308:21 309:5	contributing (4)	227:20	curve (4)	282:10,17 285:7
310:13 312:16	282:10 283:5,18	corroborates (1)	319:4,13,19,19	311:11 318:19
314:12,15,22 315:5	284:12	227:4	cut (1)	defendants (3)
315:10,16 316:1,13	control (1)	coughing (1)	293:7	212:11 213:9 218:22
316:22 318:1,20	307:4	303:25	cuts (3)	defined (1)
319:24	controlled (2)	counsel (3)	292:3 294:23 295:7	239:6
connection (2)	216:12 316:10	218:20 219:2 323:17	<hr/>	degree (1)
223:9 269:10	convincing (1)	count (6)	D	284:10
consensus (1)	272:9	296:4 301:10,16	D (7)	deletions (1)
314:25	copies (2)	302:14 303:4,5	214:1,18 215:1 216:1	321:7
consider (8)	256:1,5	counterevidence (1)	217:1 258:11,11	demographics (2)
230:14 233:5 234:4,7	copy (2)	306:17	Darius (2)	233:7,13
242:12,23 243:2	220:22 259:10	counting (1)	295:19,23	demonstrate (3)
262:21	Corey (2)	216:7	data (47)	291:11 305:20,22
consideration (3)	213:10 218:21	counts (8)	237:24 244:20 248:3	demonstrated (2)
242:18,19 243:13	correct (66)	290:2 293:7 295:25	248:8,15,16,18,25	307:19 312:3
considerations (4)	221:10 222:21,25	296:2 299:8 302:11	249:13,23 250:3,9	demonstrating (1)
232:19 241:11 242:22	223:16 224:10	302:22 303:7	251:17,18 252:10	307:22
284:2	225:12 226:5,17,18	County (3)	262:10,23 263:4,22	demonstration (1)
considered (16)	226:21 227:14,15	321:2 323:4,23	263:24 264:14,21	288:17
226:23 230:6,18	229:5,6 231:11,24	couple (3)	271:1,8,10 275:18	deponent (3)
231:4,10,13,25	234:5 245:20	232:22 234:20 314:16		
232:13,16 244:5	247:15 248:22	course (6)		
247:14 283:11	249:17,20 251:19	227:2 231:12 233:11		
298:5,9,10 303:23	255:15 260:6,7	238:5 245:5 288:16		
considering (2)	261:2,3,10,22,23	court (8)		
229:3 304:1	262:2,5 263:1,5,11	211:1 212:1 218:9,18		
constitute (1)	272:20 273:13,16	219:4 242:1 246:5		
254:5	273:17 277:6,8	271:18		

322:4,21 323:15	286:15,24 287:1	244:2 251:5 301:23	300:3	254:2
deposed (1)	293:16 300:3	302:6	doing (10)	Drs (1)
222:24	302:21 303:6	discussions (1)	233:3 236:3 242:8,10	221:22
deposition (26)	devices (2)	243:10	253:16 267:8 274:6	duly (2)
211:13 212:10 218:7	216:14 301:9	diseases (1)	284:19 307:20	219:16 323:7
218:11 219:11,24	devised (1)	234:5	313:7	E
221:22,25 222:3	264:12	disinfected (1)	Dorien (4)	E (11)
223:18,20 243:12	Diabetes (1)	302:16	211:25 212:15 218:18	213:1,1 214:1,2,13
244:10 245:17	232:22	dismissed (1)	323:2	215:1,3 216:1,3
276:15 283:8 317:1	diagram (3)	296:14	dose (6)	217:1,3
320:2,5 321:5,6	288:21 289:1 300:7	disregard (5)	287:3,12,15,16 288:7	earlier (2)
322:3 323:6,7,9,12	difference (5)	282:3,5 284:6,7 319:3	288:23	245:16 291:11
depositions (1)	274:3 275:3,9 276:3	disruption (1)	double-check (1)	editor (1)
222:1	302:21	311:25	260:13	278:4
describe (6)	different (16)	disrupts (1)	downward (2)	educating (1)
230:13 242:16 283:21	236:23 237:25,25	287:2	270:8,11	235:25
285:6 295:5 297:19	256:6 268:10 279:1	distinguish (1)	Dr (62)	effect (3)
described (7)	285:21 290:20	237:7	218:7 219:22 222:2,2	235:21 272:2 316:15
236:10 238:16 280:12	294:12 297:15	distinguished (1)	222:8 223:12,18,20	effort (4)
281:6 290:22 295:1	300:10 305:19,20	236:4	233:24 234:3,17	238:10 304:20 312:10
299:14	317:24 319:13,20	distribution (1)	236:5 242:6 244:3,6	317:8
describes (1)	differently (1)	311:24	244:15,19 245:1,18	efforts (1)
285:1	249:11	District (6)	245:19 247:25	306:16
describing (3)	difficult (1)	211:1,2 212:1,2 218:9	258:15,16,17 259:6	Eh (1)
254:15 284:14,24	312:24	218:9	259:7,9,10,10	277:25
description (5)	diminishes (1)	disturb (1)	263:20 266:9 269:6	EHP (1)
214:14 215:4 216:4	227:21	286:15	269:24 270:25	214:19
217:4 268:21	dip (4)	disturbance (1)	271:5,8,13 273:23	either (6)
design (8)	319:12,14,16,19	288:13	275:2 277:10	282:6 286:20 297:21
216:17 239:22 240:13	direct (4)	disturbing (1)	278:18 280:2 282:3	300:2 303:4 307:6
241:3 242:13,18	252:13 258:2 301:7	287:7	304:11,11 305:17	El-Ghobashy (1)
243:6,16	315:13	divided (1)	307:19 309:16	314:18
desirous (1)	direction (2)	261:15	310:7,11 312:1,5	elevating (1)
321:8	270:7 323:11	Doctor (6)	313:14,16,20 314:5	286:25
detail (1)	directly (5)	237:17,17 256:2	314:17,18 315:6	Email (1)
234:13	296:18 304:1 311:3	278:5 314:16	316:6 317:1 320:2	215:8
details (1)	311:21,21	315:23	draft (1)	employed (1)
304:4	disappear (1)	document (35)	257:21	224:2
determinates (1)	319:17	215:18 216:5,10,14	drafted (6)	employees (6)
239:4	disclosed (3)	216:21 221:1	258:15 259:7,9	305:13,17 307:19
determination (2)	230:20 231:10,23	222:15 225:21	277:22 278:1 312:6	308:17 311:20
227:10 243:3	discontinued (1)	233:18 235:7	dramatic (1)	312:2
determine (2)	214:17	250:17 251:23	311:3	encourage (1)
233:5 238:22	discovery (1)	252:1 256:8,10,14	drawing (1)	312:10
detriment (1)	251:23	259:18,19,21,23	303:24	engaged (1)
268:5	discredit (1)	289:7 292:16 293:5	drawn (1)	307:20
developing (3)	306:16	293:23 294:20	237:23	enhanced (1)
249:7,8 273:2	discuss (1)	296:22 298:22	dressings (1)	307:15
deviate (1)	295:10	299:24 300:21	318:11	entered (1)
269:13	discussed (7)	305:5,9 306:3	driven (1)	280:4
deviated (1)	220:18 231:13,22	309:10,12 312:24	238:15	enters (1)
281:12	245:16 251:18	documents (4)	driving (3)	302:13
deviation (1)	284:16,21	306:18 307:13 310:17	238:11 239:10,10	entire (2)
281:14	discusses (1)	316:3	drop (2)	308:25 312:25
device (10)	252:12	243:17 299:10,20	214:17 254:8	entitled (5)
231:6 282:19 285:6	discussion (4)		dropped (1)	

214:16 215:18	264:25 265:16	294:11 296:20,23	233:9 235:20 243:16	find (14)
216:5,10,14	272:8 277:13	297:23 298:20,23	266:7 268:18 269:4	219:25 235:21 255:21
epidemiologic (1)	278:17 281:3 284:4	300:19,20,22,25	271:11 283:21	256:4 293:3,8 295:6
241:7	284:24 288:8,20,22	302:1 305:3,4,6	312:17 318:14	297:14 305:22
epidemiological (12)	288:25 289:1,3	309:10,13 310:22	factor (7)	308:19 310:10
224:17 225:1,11	298:9 299:20	exhibits (2)	231:7 232:18 234:25	312:24 313:8
226:11 228:1,20	306:16 307:18,24	257:2 316:2	235:14 237:6 245:7	315:20
229:8,17 234:18	308:1,22 312:20	exist (2)	283:6	finding (2)
242:3,4,10	315:13	282:7 285:9	factors (20)	241:18 298:1
epidemiologist (6)	evidenced (1)	exists (1)	214:22 231:2,9,22	findings (10)
224:3,8,13 242:11	253:17	309:22	232:13,16 233:5	227:4,11,25 241:7
284:10 312:13	exact (2)	exonerated (1)	234:22 236:7,15	268:10 276:17
epidemiologists (3)	260:8 274:7	308:18	238:14,21,21,23	278:11,21 279:1
239:19 240:10 241:3	exactly (3)	expect (1)	243:14,19 247:2,13	308:25
epidemiology (5)	255:7 261:21,24	234:13	247:14 287:9	fine (1)
214:19,22 224:23	EXAMINATION (5)	experienced (1)	214:22 231:2,9,22	237:18
225:7,15	214:4,5 219:20	238:8	259:12 264:25 265:16	firm (1)
epithelial (1)	314:14 318:23	experimental (1)	277:8,12 307:25	312:8
302:17	examined (1)	228:23	308:22 312:11,18	firms (1)
equal (1)	219:18	experiments (4)	235:5 237:16 285:3	312:9
234:24	example (3)	302:12 303:3,8	300:15 306:5 307:3	first (21)
equals (1)	228:16 232:2 266:4	305:12	214:20 225:12,17	219:25 228:16 231:1
235:16	examples (1)	expert (19)	226:11,16,20	238:9 248:13
ERRATA (1)	286:4	217:5 221:16 222:8	227:12,12,17,18,21	250:22 251:4,14
322:1	exception (1)	223:3 230:11	227:24 228:9	252:5,8,14 254:15
error (2)	262:24	232:16 234:4,7	false-negative (1)	257:21,24 266:25
244:20 245:12	excuse (12)	242:1 243:20	241:10	267:1 270:18
essential (2)	225:4 230:8 231:8	246:15 282:12,15	309:16 311:1 317:1	318:5
230:8 241:15	233:15 259:9 261:6	284:3,25 295:11	fitness (1)	319:4
essentially (7)	266:15,25 273:24	296:18 297:18	false-positive (1)	five (2)
226:10 227:3,15	282:24 292:14	312:13	241:9	301:24 305:19
238:6,11 279:12	303:25	experts (1)	FAW (3)	flatten (1)
285:7	exhibit (95)	233:25	251:8 302:20 311:10	316:11
estimate (14)	214:15,19,22 215:5,8	EXPIRES (1)	FAWs (1)	Floor (1)
243:21 246:17,19	215:11,13,18 216:5	322:25	302:23	212:12
270:6 271:25 272:2	216:9,14,17,20	explicitly (1)	feel (3)	flow (10)
276:12 282:16,19	217:5 220:20,22	232:16	234:14 237:20 312:14	215:15 232:3 253:14
283:12,12,14,17	221:2,7 222:14,16	extensively (1)	feet (1)	286:16 287:1,2,7
319:10	223:9,18 225:19,22	284:2	223:25	288:13 301:14
et (12)	227:5 228:4 233:14	extent (1)	field (11)	303:11
214:24 215:16,21	233:19 239:13	226:23	216:15 286:17 287:8	focus (2)
216:8,12,16 233:16	242:7 247:4,22	eyeballing (1)	301:11,15 302:14	242:5 264:17
294:2,14 296:21	251:20 252:2	269:17	302:22,23 303:6,12	focused (1)
298:21 311:6	255:18,23 256:6,7	F	304:16	232:11
evaluated (1)	256:11,25 257:10	fabric (25)	figure (15)	focusing (1)
229:3	257:20 259:17,24	215:5 249:6,15 250:6	261:17 266:21 267:3	238:13
evaluating (1)	260:10,12,20,21	252:10,25 253:10	267:6,17 270:5	238:13
242:9	261:4,6,9,13,14,20	253:25 255:12	272:1 285:1,4,16,19	follow (6)
evaluation (3)	261:22 263:6,7	261:25 262:9,13	286:14 298:10	224:3,9 269:6 280:12
241:7 242:3 304:9	264:17 266:17	263:24 264:3	311:15,18	293:18 318:25
events (1)	268:19 269:1,12,19	265:14 266:3,12,15	final (1)	followed (5)
317:9	269:25 271:2	267:1,14 268:4	266:10	263:19,21 264:19
evidence (31)	272:22 273:14	270:2,13 275:5	finally (2)	265:3,4
224:18 225:2,8	276:21 277:16	276:4	271:8 316:25	
226:23 228:1	289:6,8,18,23 291:6	fact (10)		
241:13 242:4 253:5	293:22,24 294:3,5			

following (3) 223:2 267:24 280:1	305:13	296:13 297:10 305:16 306:2 307:6 311:18	308:13 309:2,9,15 310:21,24 313:12 313:23 314:5,19 315:2,8,15 316:3,12 316:17,19 317:20 318:8,16,24 319:22	healthcare (2) 232:9 253:8
follows (1) 219:18	241:12	fraught (1) 226:11	go (18) 228:3 229:7 232:20 239:13 246:1 247:21 261:4 266:24 267:1,5 273:11 278:1 285:20 290:3	heat (2) 254:6 287:1
forced (5) 211:4 212:4 216:14 218:8 268:8	234:14	free (1) 242:17 298:1 309:8 318:7 319:8	gotten (1) 237:24	held (1) 218:11
forced-air (38) 214:16 248:4,6,17 249:7,19,25 250:8 252:18 253:22 255:8 258:5 261:1 262:7,13 264:1,11 264:13,22 265:3,13 265:19 266:10 268:9,23 269:11 270:13 272:22 273:3,12,19 275:3 276:3 281:5 282:18 293:15 301:9 303:6	268:17 301:8 310:1 319:1,21	front (5) 242:17 298:1 309:8 318:7 319:8	grabbed (1) 255:20	helpful (1) 226:24
foregoing (2) 321:6 323:6	304:6	full (5) 242:17 298:1 309:8 318:7 319:8	great (4) 235:12 278:20 295:17 314:10	hereto (1) 323:16
form (19) 229:22 238:25 245:23 264:4,24 271:17 272:10 274:22 276:6 299:20 301:18 303:14 312:17 314:19 315:2 316:12,17 317:20 318:16	317:15	further (7) 264:14 276:16 303:17 318:21,23 319:23 323:17	greater (7) 234:24 235:18 236:6 291:9 294:24,25 295:7	hereunto (1) 321:10
formal (2) 317:5,7	304:6	funded (1) 304:6	Gregory (1) 215:16	high (3) 253:15 275:5 281:13
formed (1) 311:16	317:15	gap (1) 263:4	ground (3) 221:14 222:11 230:17	higher (6) 247:10 274:21,23,25 319:10,11
forms (1) 311:16	323:17	gathered (1) 237:24	group (3) 236:4 310:2 312:5	highlighted (1) 231:14
formulation (1) 300:6	323:17	general (6) 225:14 237:19 238:19 241:25 245:10 296:3	grown (1) 228:2	hip (14) 248:3,25 249:24 251:8,17 254:25 262:11,14,21 266:8 268:1 273:15,24 276:10
forth (3) 271:2 318:3,9	323:17	generalization (1) 226:15	growth (2) 301:19 303:15	hips (6) 250:15,21 251:2 265:11,12 266:2
forward (1) 319:10	323:17	generally (8) 224:22 228:11,22 232:7 239:22 240:13 242:8 307:8	guess (4) 219:25 224:11 225:4 251:4	hired (1) 312:5
found (4) 293:11 296:11 300:13 302:25	323:17	generate (4) 225:8 227:24 243:22 246:21	guide (6) 216:22 309:20,22 310:11 312:6,9	history (1) 304:23
foundation (2) 254:17 310:13	323:17	generating (1) 225:12	H	Hedges (2) 216:20 310:4
four (4) 272:14,15 301:24 302:12	323:17	generic (1) 226:16	H (4) 214:13 215:3 216:3 217:3	hold (2) 246:5,13
fraction (1) 291:8	323:17	getting (1) 307:2	hand (4) 219:7 220:14,16 236:21	holding (1) 246:4
fractionated (2) 291:23,23	323:17	give (11) 219:11 220:22 235:5 237:14 245:10 255:19 273:20 274:7,7 281:7 294:17	handed (1) 306:2	Holford (5) 221:17,22 222:2 318:10,25
frame (1)	323:17	given (13) 220:11 231:17 262:3 266:1 268:21 275:23 280:11	happened (3) 232:25 313:13 317:9	Holford's (5) 244:2,6,15 245:19 317:1

218:7 231:6,17 243:17 248:17 263:16 264:20 265:10 266:2,14,16 267:13 270:1 271:6 282:9,19 283:5 284:11 285:6,9 286:5,10,15,24 287:11,24 288:3,6 291:11,13,18 292:19 293:12 295:25 299:9,19 300:3 305:18,21 307:21,23,24 308:17,18 309:21 311:4,10,23,25 312:3 315:14 319:5	implemented (1) 319:9 implicit (1) 251:3 implied (1) 312:25 import (1) 278:14 important (2) 233:4 298:7 improper (1) 280:7 improvement (1) 268:3 inaccurate (1) 277:11 include (1) 254:24 included (4) 250:14 286:7 317:12 317:14 including (2) 225:17 318:10 incorporated (2) 218:16 238:1 increase (13) 216:14 238:8 288:23 291:13,19 293:11 301:10 303:4,19,20 311:11 312:4 315:13 increased (16) 235:2 236:7,8 282:21 287:3,3,12,14,15,16 287:18 288:3,4,14 288:17 292:12 increases (6) 287:24 288:8 291:12 295:25 301:15 311:24 increasing (2) 288:7 296:1 independent (3) 234:25 235:13,21 indicate (4) 249:14,24 263:3 310:1 indicated (2) 229:23 231:25 indicates (1) 243:13 indicating (2) 260:23 285:13 indication (2) 226:25 296:1 indicator (1)	296:5 indispensable (2) 229:11 230:9 individual (4) 239:3,5,6 313:3 individuals (2) 233:1 239:11 industry (7) 280:17 281:9 306:12 306:23,25 307:1,4 infection (50) 214:17 215:11 216:5 233:4 234:19,20 235:2 236:9 237:8 238:24 239:3,6,7 244:4 245:2 246:23 248:3,8,25 250:20 250:24 252:17,23 253:17,24 254:1,7,8 254:10,20,23 259:22 262:11,18 264:22 265:12 266:16 268:3 269:19 270:16 271:2 274:3,5,10 282:17 285:8 295:21 300:8 318:19 319:4 infections (40) 214:23 215:6 216:22 232:10 234:8 235:16 238:7,12,16 249:7,8,15,20 250:1 252:11 253:7 254:15,25 258:7 261:11 262:12,14 263:10,13 264:1 267:13 270:17 272:15 273:1,2,25 279:4,9 282:11 283:6 284:12 287:11 311:5,12 318:5 infectious (8) 234:4 287:4,12,16 288:4,7,14,23 influence (1) 272:4 information (10) 214:7 265:18 277:18 277:23 283:22 296:13 303:23 304:18 307:8 317:24 initial (1) 317:23	309:21 issue (6) 230:13 246:16,20 298:13 314:23 317:18 issues (1) 224:22 itis (2) 301:18 303:14
J			
Huggers (1) 292:11		Jan (4) 213:4 218:23 255:21 256:23	
humps (1) 318:5		Jarvis (5) 233:17,24 234:17 314:17 315:6	
hypothetical (6) 259:1 265:2 278:14 286:4,9,12		Jarvis's (2) 234:3 242:6	
I			
identical (1) 257:17		JNE/FLN (3) 211:4 212:4 218:10	
identification (14) 221:3 222:16 225:22 233:19 252:2 256:11 259:24 289:8 293:24 296:23 298:23 300:22 305:6 309:13		JOB (1) 211:24	
identified (1) 235:11		joins (1) 283:8	
ignored (1) 280:3		joint (36) 214:17 215:5,11,15 216:22 233:4	
II (1) 211:5		234:20 235:2 236:9 237:8 244:4 246:23	
impact (13) 242:14 246:25 269:21 270:3,12 276:2,12 304:5,9,19 318:2,10 318:11		248:3,8,25 250:1,19 250:24 251:9 252:11 254:25 258:6 259:22	
impair (1) 228:21		262:18 268:3 269:19 282:10,17	
implant (4) 215:6 252:11 253:6 279:4		283:6 284:12 285:8 287:11 311:5,8,12 318:19	
implausible (1) 313:8		Jonathan (10) 211:13 212:10 214:3 217:5 218:7 219:15 320:2 321:4,13 323:5	
implement (1) 317:15		Jordan (2) 213:15 218:15	

231:20 276:14 317:16 319:3,4,8 justification (1) 245:13	K Kennedy (2) 216:20 310:4 kept (1) 307:23 kind (6) 224:20 225:19 237:11 281:7 292:3 293:18 knee (28) 214:23 234:19,20 235:14 239:8 248:3 248:25 249:24 251:9,17 252:16,23 253:6,23 254:15,20 255:3 260:4 261:5 261:12 262:11,14 262:21 266:8 268:1 273:15,25 276:10 knees (13) 250:15,21 251:2 260:20 261:9,20,22 263:9,25 264:17,19 264:23 280:3 knew (2) 259:6 316:4 know (32) 221:13 227:22 228:10 233:24 234:12,15 242:13 243:4 244:21 245:5 247:1 255:25 256:2,4 258:3 264:5 270:9 275:8 281:10 284:22 293:17 295:3 297:25 304:6 304:10,20,23 306:6 306:18 308:11 309:7 313:9 knowing (1) 277:10 knowledge (8) 241:15 258:15 299:6 307:12 308:5 310:4 310:8,9 known (1) 253:15	286:1 labelled (1) 218:6 lack (2) 254:16 310:13 laid (7) 284:25 288:2,11 298:3,10 300:6 313:5 laminar (6) 215:15 232:3 253:14 301:14 303:11 311:25 Lancet (2) 313:15,20 Landrin (2) 216:8 296:21 larger (1) 276:11 law (5) 213:4,4,10 312:8,9 lawyers (1) 312:6 lay (2) 282:13 288:25 lead (8) 242:21 246:17 247:3 262:20 275:18 283:23 286:10 287:3 Leads (2) 213:15 218:15 learn (2) 258:14 310:6 left (1) 243:6 legal (2) 218:16 219:2 legitimate (5) 308:24 313:2,9,17,19 let's (9) 225:25 239:13 247:21 249:2 269:7 284:20 286:13 287:20 313:23 level (2) 232:24 296:6 levels (1) 303:19 liability (6) 211:4 212:4 216:23 218:8 309:20 312:7 light (1) 297:15 likelihood (1) 227:20	291:21 292:8,13,18 294:19 297:18 299:22 300:11,16 308:17 319:13,18 319:20 looked (8) 220:4 234:22 236:14 236:20,23 237:1 265:11 267:9 looking (11) 233:6 238:4 247:4 248:15 250:18,21 251:1 264:19 291:2 292:14 315:21 lopped (1) 319:15 Los (7) 211:14 212:13 218:1 218:12 321:2 323:4 323:23 lost (1) 274:13 lot (5) 221:14 230:16 231:20 243:25 267:7 low (3) 272:8 302:24 303:7 lower (8) 265:21 267:18,22,23 270:6 272:1 275:4 318:6 Luisa (1) 215:20 lung (1) 224:14	M M (2) 214:24 217:5 M.D (11) 211:13 212:11 214:3 215:16 217:5 219:15 258:11,11 321:4,13 323:5 M.S (1) 217:5 magnitude (3) 283:10,20 284:15 main (2) 228:6 253:7 major (1) 233:12 making (1) 321:8 malfunctioning (1) 232:3	manipulated (1) 281:9 manuscript (1) 243:7 March (5) 217:6 221:10 223:19 232:1,12 mark (6) 215:8 216:19 222:13 256:6,15 260:10 marked (24) 217:3 220:21 221:2 222:15 225:19,21 233:18 252:1 255:18 256:8,10 259:23 289:7 293:23 296:22 298:20,22 300:19 300:21 302:15 305:4,5 309:10,12 Marla (1) 215:20 material (2) 278:3 295:18 materials (23) 220:1,3,5,12,13,16,19 221:5,7,8 223:7,8 223:10 224:4,12 243:8 248:11 262:17 269:14 277:6 280:13 294:4 299:3 math (6) 261:15,17 266:21 267:8 273:20 274:19 matter (3) 244:18,24 278:4 matters (1) 280:25 McGovern (48) 216:16 226:20,22 227:2,9,11 229:3,17 229:23 230:5,12,19 232:14,17 233:8 243:5 246:7 247:15 250:20 256:8,25 258:11,16,17 259:2 259:6,9,10 276:17 276:24 282:4,4,15 282:16,24 283:1,12 284:7 300:19,25 304:11,12 311:6,6 311:18,21 313:2 318:15 McGovern's (1)
---	--	--	---	---	--

316:6	220:3	model (2)	245:7 288:7 292:13	269:1,12,18,23,25
MDL (2)	mentioned (7)	285:5 290:4	293:3	274:2,7 275:8
211:4 212:4	232:14,18 245:15	modeling (1)	neither (2)	277:10 286:25
mean (33)	295:19 296:18	290:3	247:13 323:17	288:14,17 290:5,9
230:11 231:1 233:10	315:11 317:4	models (2)	network (1)	302:25 309:11
235:9 238:5,19	met (2)	290:1 291:9	253:8	O
250:9,9 256:24	219:23 220:1	moment (2)	never (3)	oath (2)
258:20 265:17	method (1)	292:13 294:17	306:7,8 312:4	219:16 323:8
266:20 268:7 269:8	251:12	Monitoring (1)	new (1)	object (10)
270:6,6,11 271:21	methodological (1)	216:5	220:5	229:21 237:10 245:21
272:15 277:15	280:7	Mont (1)	night (1)	312:16 314:19
282:12 286:21	methodologies (1)	222:8	244:10	315:2 316:12,17
295:13 297:24	225:8	month (2)	non (1)	317:20 318:16
298:15,15 301:1	methodology (1)	219:23 221:24	215:15	objection (21)
306:15 307:2,11	224:8	months (4)	noncausal (2)	230:21 238:3,25
308:4,5 317:6	methods (5)	233:12 248:7,19	239:21 240:12	254:16 255:1 264:4
means (1)	238:10 248:11 262:17	263:23	North (2)	264:24 265:15
317:22	269:14 280:13	Mordecai (2)	212:12 218:12	266:19 268:6
meant (1)	Michael (2)	213:16 219:1	nosocomial (1)	271:15 274:22
317:7	213:4 222:8	Moretti (1)	234:8	275:13 276:6 280:9
measure (3)	microbes (1)	315:12	notable (1)	305:23 307:25
290:25 291:1 292:5	286:25	morning (1)	303:3	308:21 309:5 315:8
measured (7)	microbial (3)	219:22	Notary (1)	315:15
290:7,13,15,18	215:19 286:16 287:8	move (1)	322:25	objective (1)
291:25 292:1	216:7	237:13	note (1)	224:4
302:11	middle (5)	movement (1)	253:22	observation (1)
measurements (1)	228:17,17 239:17	224:14	noted (1)	251:6
300:4	240:1 319:12	moving (1)	301:12	observational (5)
measures (1)	Mike (1)	319:9	notion (1)	228:19 233:3 282:4
291:24	218:24	MSSA (2)	295:24	283:2 284:6
measuring (3)	million (1)	232:2 318:11	November (2)	observations (1)
290:21 299:18,21	275:6	multicenter (9)	215:10 311:7	226:10
mech- (1)	mind (1)	251:6 269:21 270:3,7	number (55)	observed (2)
287:10	244:13	272:23 273:3	214:14 215:4 216:4	231:5 282:14
mechanism (3)	Minneapolis (2)	275:12 276:2 280:5	217:4 218:6,10	obtained (1)
286:11 287:7,23	213:6,12	MyHealthcare (1)	225:16 231:22	221:23
mechanisms (4)	Minnesota (7)	253:19	246:1 249:7,8	obtuse (1)
229:10,20 230:8	211:2 212:2 213:6,12	MyHealthcare.com...	251:22 253:18	239:14
285:2	218:10 253:9,19	253:20	255:6,7,8,12,14,23	obviously (2)
mechanistic (12)	minute (1)	<hr/> N	259:18 260:8,19,20	278:13 307:11
282:13,21 283:22,22	293:3	213:1 214:1,2 215:1	260:25 261:5,7,8,19	occasions (1)
284:8,20,24 287:10	mischaracterizes (2)	216:1 217:1	266:24 267:21	305:20
287:25 298:10	305:24 308:1	name (6)	268:22 272:6,7,21	odds (18)
300:6 312:1	misleading (3)	218:15 259:11 312:7	273:1,2,12,15,19	243:23 244:3,6,15,15
mediated (1)	278:7,18,24	312:8 321:11 322:2	274:4,8,12,16,18	244:17 245:15,19
288:3	missing (1)	named (1)	281:13 287:4,18	246:8,8,10 275:6,11
medical (12)	230:25	323:5	288:4,8 289:14	275:19,25 276:1
215:6 236:21 251:25	misstates (3)	narrow (1)	290:18,19 291:12	279:7 281:13
252:12 259:20	230:21 312:18,18	314:7	302:1 314:5	offer (2)
269:2,3,5 270:25	misuse (2)	nature (1)	numbered (1)	228:14 246:5
271:3,7 284:11	280:16,21	269:9	301:23	offering (4)
medicine (1)	misused (1)	necessarily (1)	numbers (28)	242:1 271:22 284:9
224:13	281:9	231:2	249:11 252:14 255:10	284:17
meeting (1)	mode (1)	need (4)	257:16 261:20,24	Offhand (1)
251:16	270:18		265:20,24 266:1,8	222:9
memory (1)			267:12 268:20	

office (1) 219:1	216:15 301:11,15 302:14,21,23 303:6 303:12,21	249:3,4 251:21 255:2 257:10,12,20 257:21,22,25 285:11,16,19 286:13 298:4 301:8	particle (11) 216:6 290:2 296:4 302:11,14,17,22 303:4,19 311:24,24	277:25 278:2 298:12 306:19 307:9
Oguz (2) 216:12 298:21	opine (1) 283:4	285:11,16,19 286:13 298:4 301:8	particles (22) 224:15 288:18 289:19 289:24 290:15,18 291:1,5,12,12,16 292:1 294:15 297:16 298:6,14 299:21 300:7 301:13,18 303:10 303:14	penalty (1) 219:10
Oh (4) 240:5 257:1 271:16 276:25	opinion (14) 221:10 222:8,23 226:19 227:9 230:1 232:1 246:6 282:9 284:10,18 287:25 294:13 295:11	301:25 302:6 310:1 310:22,23 315:17 315:22,24	particular (13) 236:10,16 237:22 238:7,16 247:6,7,7 247:9,11 248:20 295:16 313:18	people (3) 300:2 304:11 313:21
Okay (74) 220:6,17 221:13 222:1,6,10 223:11 223:15,24 226:6 228:3 229:7 233:2 234:12 237:1 240:5 240:8,20 241:20 242:5 245:7 247:4 248:12,23 249:10 250:13 251:12 252:8 253:3 255:11 257:4,6,19 259:17 260:4,25 261:4 265:8 270:22 271:21 272:12 273:11 274:1,16 276:20 284:20 286:13 287:6,22 288:22 289:3,16 293:20 296:16 298:18 299:17 301:5,22 302:4,9 305:11 309:25 314:23 315:11 316:2,9,23,25 317:4 317:11,17 318:2,8 320:1	opinions (8) 224:9 228:14 229:24 245:9 246:4,13,25 271:14	225:25 226:20,22 227:2 228:4,9,10 229:4,4,17,18,24 230:5,19,20 231:23 232:14,17,21	particularly (2) 230:12 282:14	percentage (2) 267:23 274:10
old (2) 221:14 222:10	order (4) 224:9 243:3 290:24 321:8	233:22 238:5 239:2 239:15 243:10 246:10 247:9,15,21 248:1,14 249:3	particulate (2) 215:19 295:25	performed (2) 215:15 305:12
omission (1) 268:23	organisms (10) 287:1,4,13,16,19 288:4,7,14,23 292:19	255:7 257:15 259:11 261:2,25 262:4,6,21 263:2,3	particulates (2) 215:14 314:24	Peri-Prosthetic (1) 216:21
omitting (1) 271:9	original (1) 222:23	263:20 268:20 269:4,6 270:25	party (1) 323:18	period (28) 233:12 243:17 248:5 249:15,19 250:3,10
once (1) 245:15	orthopedic (5) 214:15 216:11 253:6 299:10,18	271:8,13,19 272:5,8 275:2 276:16,17,23 276:24 277:2,11,17 277:21,22 278:1,2,6	pass (1) 314:9	255:8 261:1 262:1,8 262:23,24 263:21 263:23 264:2,3
one-year (4) 263:3,21 266:15,15	ostensibly (1) 312:8	278:11 279:22 282:5,5,15,16,20 289:6 290:15 291:6	passive (1) 290:20	265:4 266:11,11,16 270:2 274:11
ones (1) 221:5	outbreak (2) 236:11 238:11	294:2,11,12 295:10 295:12,20,23,24 296:7,21 297:13	path (2) 224:19 287:14	317:23 318:6,7 319:6 323:16
online (1) 317:16	outcome (3) 251:7,11 323:19	298:20 299:5,22 300:1 304:12	pathogen (2) 301:19 303:15	periods (6) 231:18 232:25 233:10 247:19 251:18
open (1) 309:7	outcomes (2) 224:23 290:1	311:21 313:18,20 313:22	pathogenic (1) 287:17	271:3
operated (3) 235:11,18 247:11	outside (2) 301:14 303:11	papers (8) 226:14 227:19,24 268:25 269:4 289:21 311:22 313:15	pathogens (3) 301:17 303:13,21	periprosthetic (6) 214:17 250:19,24 258:6 262:18 311:4
operating (6) 215:15,20 216:6 232:4 294:16 303:1	owner (1) 281:4	paragraph (8) 228:17 236:21 238:9 240:24 248:11 302:9 311:1,1	pathway (1) 288:1	perjury (1) 219:10
operative (9)	<hr/> P <hr/> P (4) 213:1,1 226:24 227:22	part (14) 226:19,22 227:10 235:3 248:13,23 286:2 287:25 294:3	patient (6) 233:7,13 235:11 238:14 239:7 302:18	person (1) 237:8
	page (38) 214:3,14 215:4 216:4 217:4 228:16 236:21 239:15	298:9 304:12 306:25 307:12 314:17	patient- (1) 238:22	pertinent (1) 241:13
			patient-specific (4) 232:19 233:5 238:20 247:14	Pg (1) 322:5
			patients (4) 234:23 236:5,22 247:7	phases (2) 239:23 240:14
			Paul (1) 258:11	phonetic (6) 228:7 289:6 295:19 313:14 314:18 315:12
			peer (11)	physician (1) 238:15
				physiology (1) 224:19
				picked (2) 280:3 299:16
				picture (1)

224:21	populations (1)	213:14 228:23 286:11	225:11	pull (1)
pie (2)	215:14	presentation (1)	proof (1)	223:25
285:21 286:2	pos- (1)	294:22	254:5	pulled (2)
piece (1)	227:12	presented (5)	proper (1)	270:7,8
285:15	posed (1)	249:11 277:4,21	233:3	purported (1)
pieces (4)	226:14	278:9,21	proposed (1)	267:25
288:13,21,25 289:3	positing (2)	presenting (1)	proposition (4)	purporting (1)
pilot (1)	227:10,24	280:7	238:20 241:25 246:7	311:22
216:12	position (2)	pretty (2)	289:19	purpose (4)
PJI (2)	226:10 283:4	244:11 279:19	protocol (24)	259:5,12 310:18
251:8 314:25	positive (4)	previously (8)	248:2,13,24 249:22	317:10
PJIs (1)	226:21 227:12,18	217:3 221:2 256:7	250:22 262:7	purposes (11)
311:5	247:9	271:18 279:6	263:20 264:12,19	236:16 263:14,17
place (3)	positives (8)	284:16 300:19	265:3 266:9 267:25	264:16 265:9
250:6,7 251:1	214:20 225:12,17	305:3	268:1,10,14,17	266:13 270:23
plaintiffs (3)	226:12,17 227:21	principles (2)	269:6,13 271:5	279:24 282:6
213:2 218:24 233:25	227:24 228:9	228:12,13	278:23 280:1,12	308:14 311:19
plaintiffs' (3)	possibility (3)	prior (5)	281:12 290:23	pursuant (3)
312:6,8,9	231:4 283:23 284:1	221:9 232:1,12 319:3	prove (1)	251:24 256:15 259:20
plausibility (2)	possible (2)	319:7	278:16	put (1)
282:13 284:3	251:7 303:20	probability (2)	224:18	224:18
plausible (1)	postulate (1)	283:24 284:1		
282:21	247:2	probably (4)		Q
playing (1)	potential (23)	255:2 268:19 269:12		quality (1)
238:23	229:9,19 230:7,11	277:22 278:11		253:15
please (5)	231:1,3,7,9,13	323:15		quantitative (6)
218:20 219:4 230:24	233:6 239:20	provides (2)	282:19 283:14,16,19	282:19 283:14,16,19
237:19 259:12	240:11 242:12,14	276:16,23	284:14 296:13	
PLOS (1)	242:20,25 243:1,21	providing (1)	quarrel (1)	
215:18	246:16,20 303:9,12	281:3	244:14	
plow (2)	318:9	proximal (1)	question (52)	
225:20 230:16	potentials (1)	233:9	224:6,21 227:9	
plowing (1)	241:9	proxy (1)	229:22,25 230:3	
221:14	PowerPoint (1)	314:24	231:15 235:4	
plus (7)	260:14	public (8)	237:18 244:13	
272:16,16,18,18,24	practice (1)	214:20 225:6,9 241:5	245:24 246:12	
273:4,10	281:15	241:15,22 312:13	252:5 258:22 259:5	
point (15)	pre-July (1)	322:25	259:12 263:15,17	
235:4 242:22 243:2,5	319:16	publication (11)	265:9 266:13	
245:8 247:1 252:15	predicated (2)	221:15 226:8 227:6	267:15 268:12	
252:21 270:4,19	227:9 278:12	227:17 231:11,14	269:7 270:23	
273:22 274:24	Predict (1)	233:15,16 259:16	271:23 275:16	
296:3 300:5 319:11	215:19	267:25 277:6	278:12 279:24	
points (1)	predicted (1)	publish (6)	282:6 285:19 290:6	
294:23	291:3	304:20 306:17,18	290:10 291:15	
pool (1)	Predicting (1)	307:9,23 309:7	292:17 297:16	
275:20	215:13	published (28)	298:5,7,17 307:10	
pooled (9)	premise (1)	220:12 223:2 243:7,9	308:9,14 309:3	
269:21 270:3 272:2	229:25	246:9 248:1 263:2	310:15,19 311:19	
272:23 273:3	preparation (2)	268:20,25 271:13	312:17,22 314:20	
275:12 276:2,12	223:3 259:2	272:9 277:22	315:3 316:19	
280:5	prepared (1)	278:11 298:12	317:21 318:17	
poor (2)	246:5	299:14 305:17	questioning (2)	
224:5,5	presence (1)	307:8,21 308:11,12	244:25 278:3	
population (3)	296:5	308:12,17,19 309:1	questions (5)	
225:7 248:21 291:3	present (3)	311:7 312:5 316:4	214:10 225:6 278:10	
		318:13		

314:16 318:21	237:12,15,17 240:9	reduce (2)	relative (3)	218:18 219:4,6,9
quick (4)	244:10 248:14	253:16 275:20	246:21 275:23 290:1	221:3 222:17
281:19 285:18 313:23	251:14 252:19	reduced (3)	relatively (1)	225:23 233:20
318:25	253:1,3 254:12	253:6 270:18,19	272:7	252:3 256:12
quickest (1)	262:10 300:10	reduction (5)	relevant (3)	259:25 289:9
234:16	301:2 302:10	215:5 252:11 275:19	225:6,9 277:17	293:25 296:24
quite (3)	319:25 321:6 322:5	279:4,8	reliable (1)	298:24 300:23
227:25,25 282:21	reader (1)	Reed (3)	282:8	305:7 309:14 323:1
quote (3)	262:20	304:11,16 313:2	relook (2)	323:3,15,22
225:17 227:21 231:15	reading (21)	Reed's (5)	304:2,3	reporting (4)
R	228:18 229:7 235:9	244:3,19 245:1,18	relying (4)	218:16,19 273:24,25
R (1)	238:9 239:18 240:9	246:19	246:9,13 291:18	reports (4)
213:1	241:1 250:23 251:5	refamiliarized (1)	314:17	221:17 275:2 279:3
raise (3)	252:9,15,22 253:4	223:6	remember (7)	318:10
219:6 276:25 278:20	253:13 258:4 262:6	refamiliarizing (1)	221:19,20 222:6,9	represent (8)
raises (1)	262:6 301:8 302:10	292:14	257:8 301:3 316:20	226:20 227:11 251:22
278:10	303:16 311:2	refer (1)	remind (1)	256:14 259:19
random (1)	Reads (1)	278:4	316:24	281:14 302:17
290:9	322:5	reference (6)	render (2)	305:11
randomized (1)	real (1)	251:3 254:19 294:4	276:3 321:8	represented (2)
216:12	282:23	295:10,14 299:2	rendered (2)	262:10 278:10
ranking (1)	realize (1)	referenced (2)	221:9 222:23	representing (1)
253:18	226:9	254:24 276:15	rendering (2)	297:4
rate (16)	really (4)	referring (3)	232:1,12	reputations (1)
234:19 252:17,24	235:5 258:19 301:3	280:24 291:10 313:19	repair (1)	313:22
253:24 254:2,10,20	313:6	refers (2)	232:2	requested (3)
260:5 262:11	reason (5)	255:3 262:21	repeat (1)	214:7 323:14,14
265:12 266:17	244:14 245:14 282:7	reflect (1)	312:22	required (1)
267:11,16,16	319:15 322:5	269:2	repeated (1)	303:17
274:10 319:4	reasonable (2)	reflected (3)	261:18	rereviewed (1)
rates (20)	229:1 284:10	260:20 270:24 271:4	rephrase (1)	223:5
214:17 215:12 233:4	reassuring (1)	reflection (1)	research (19)	216:18 220:7 224:16
234:20 238:24	303:8	318:6	225:8 234:11	225:8 234:11
239:3,10 250:25	recalculation (1)	reflects (2)	239:23 240:14	239:23 240:14
254:8,23 259:22	245:19	224:12 271:2	253:20 305:16	253:20 305:16
267:10 268:3	recall (13)	refresh (1)	replow (1)	306:13,24 307:5,20
269:19 271:3 274:3	220:20 222:7 223:21	220:23	222:10	308:24 310:25
274:5,10 295:21	232:5,20,23 244:1,8	refreshed (1)	report (37)	311:3,9,10 312:2
318:19	244:9 291:5 304:1	220:3	216:18 217:5 220:21	researcher (1)
ratio (16)	316:9 319:12	regard (3)	221:8,12 223:3	304:16
243:23 244:3,6,15,17	received (1)	220:4 278:9 295:20	227:3 229:22	researchers (2)
245:16,19 246:8,10	278:2	regardless (1)	230:11,12 232:16	289:23 304:10
275:6,11,19,25	recess (2)	287:6	234:2,3 243:20	respect (7)
276:1 279:7 281:13	281:24 314:2	regional (1)	246:15 271:19	305:18 314:8,23
raw (2)	recognize (1)	253:8	279:2,3,18 282:12	316:2,25 317:11
266:1 267:12	254:4	regression (2)	282:15 283:11	319:14
re- (1)	recollection (4)	235:10 290:4	284:3 285:1,11	response (4)
229:16	220:23 292:10 293:10	related (4)	288:12 289:2,4	226:8,13 242:24
reaching (5)	295:17	243:8 284:3 307:5	292:8,13 296:19	245:11
287:4 288:4,19 291:4	record (10)	323:18	297:19 311:16	responsibility (1)
292:19	222:12 234:10 281:23	relates (3)	315:12,19,20 318:3	241:2
read (30)	282:1 305:24 308:2	268:18,19 318:15	reported (5)	restate (3)
221:16,21 222:2,7	312:18 314:1,4	relationship (3)	264:22 273:23 275:10	230:2 284:13 291:15
223:19,22 234:2,3	320:4	251:8 290:2 303:18	277:1,10	result (2)
234:14 235:3,6,9	records (2)	relationships (1)	224:10	275:10 276:2
	236:22 313:10			

resulted (1) 250:1	248:21,25 249:8 250:1 251:18 255:5	Sacchet (3) 213:4 218:24 260:16	232:2 318:12 scrutinized (1) 229:19	separation (1) 247:19
results (15) 225:15 226:25 230:14 268:19 269:21 270:3 272:23 273:3 275:12 277:1 280:5 302:20 307:22 308:11 318:15	255:8,20 257:5,8 261:6,9,12,16 262:1 262:4,15,16,22,25 263:4 266:17 267:2 267:5,14,22 268:5 269:16 272:17,19 272:24 273:4,9,12	safe (1) 307:24 Saito (4) 211:25 212:15 218:18 323:2 sake (2) 258:22,22	229:8 230:7,19 search (6) 297:14,20,22 298:3 298:12 299:13 searches (4) 297:19,25 299:13,15	series (2) 264:12 317:7 set (11) 244:20 247:2 271:1 278:22,23 290:11 290:25 312:7 317:10 318:3,9
retained (1) 233:25	273:19 274:4,12,21 275:5 276:18 277:4	Samet (16) 211:13 212:10 214:3 217:5 218:7 219:15 219:22 220:22 257:20 282:3	227:3 236:20 239:15 248:10,23,23 249:2 257:20 302:9	Seventh (1) 213:11 sharp (1) 238:8
revealing (1) 295:2	279:4,9,20 281:1 283:18,24 285:10	sample (1) 276:9	secret (1) 307:24	shedding (1) 302:18
review (11) 223:8 224:11 230:11 237:5 277:4 278:3 295:14 297:11 298:16 307:9 323:13	285:12,18,22,25 286:18 287:13,17 287:21,25 288:9 289:20 291:1 293:8 295:15 296:2,9,17 297:12 304:14	sampling (4) 215:19 216:6,7 302:23	secrets (1) 307:14	SHEET (1) 322:1
reviewed (19) 220:1,13,16 222:20 222:22 229:23 230:5 236:22 246:10 251:15 289:1,4,11 295:17 296:8 297:2 298:12 306:19 316:6	306:13 307:1 310:2 311:17 317:14	see (21) 236:24 239:13 240:5 256:18 257:1 258:8	section (2) 240:25 301:21	shorthand (3) 287:20 323:3,22
reviewer (6) 277:3,5,9,15,21,25	rings (1) 315:20	saw (1) 260:8	see (21) 236:24 239:13 240:5 256:18 257:1 258:8	show (21) 225:18 233:14 251:20
reviewing (7) 229:16 235:7 250:17 292:16 293:5 294:20 299:24	rise (1) 302:14	saying (3) 249:23 273:25 319:2	258:12 260:2,21,25	255:17 259:17
Reviews (1) 214:15	rising (1) 319:13	says (12) 248:11 250:22 252:9 252:15,21 253:3 258:4 262:17	261:20 263:9 275:9 290:17 301:20,21 309:25 310:25 311:13 313:24 317:9	267:12 270:12
Rhetoric (1) 214:20	risk (19) 214:22 233:13 234:25	seeing (1) 301:4	seen (13) 233:22 243:8 252:6 297:13 299:5	286:5,9,22 289:5
Ridgeview (15) 215:6 251:24 252:12 259:20 263:15 266:14 269:2,5,10 270:25 271:7 274:11,17 276:21 280:1	235:2,13 236:8 237:6 239:10 246:21,23 272:7,8 279:14 282:17,21	scenario (1) 313:5	300:17 303:20 305:9 306:7,8	293:22 296:20
Ridgeway (2) 269:3 271:3	284:15 287:14 288:3 311:17	science (6) 241:16,23 280:16,23 280:25 309:7	309:16 312:23 318:13	298:19 300:18
right (103) 219:3,6 221:11,20 223:1,5,24 224:5,24 225:3,4 226:4 230:9 230:20 232:15 234:9 236:7,12,15 236:21 238:2,24 240:16,18 242:11 242:15,23 243:3 245:14 246:4 247:8	risks (3) 239:4 279:17 307:14	scientific (6) 224:1 241:13,14 254:5 281:15 308:24	sees (1) 277:5	302:12 303:3 305:3
	RMC (2) 215:11 259:22	scientifically (1) 242:12	segregating (1) 237:2	309:9 311:22
	RMC000025 (1) 251:22	scientist (2) 306:11 312:13	selective (1) 308:10	315:13
	RMC000039 (1) 259:18	scientists (1) 309:7	sell (1) 281:5	showed (1) 292:11
	role (2) 227:23 238:23	scope (1) 298:1	senior (1) 233:16	showing (1) 222:14
	rooms (1) 215:15	score (1) 236:6	sense (1) 313:1	shown (8) 235:20 261:21 268:2
	roughly (1) 246:22	scores (4) 236:15 237:3,22 238:1	sensitivity (1) 298:1	268:4 269:25
	Ruken (1) 216:12	Scott (3) 214:18 215:9 258:11	sent (3) 258:16 259:10 312:9	291:13 292:3
		screening (2)	sentence (3) 235:9 250:22 251:4	302:24
				shows (3) 247:9 260:5 311:10
				side (3) 228:1 242:18,19
				sign (1) 319:25
				Signature (1) 322:21
				signed (1) 313:18
				significant (13) 235:1,13 237:6 247:6

significantly (2) 236:8 292:11	268:4	spent (2) 231:20 243:11	Steven (1) 214:24	subsequently (1) 223:22
similar (3) 227:25 281:8,8	slightly (4) 249:11 267:22 274:12 276:1	ss (1) 321:1	Stocks (7) 215:16 289:6 291:6 294:12,24 295:10 295:23	substantial (7) 276:12 282:10 283:5 283:18 284:11,16 288:20
similarly (1) 227:16	small (2) 317:5,10	SSI (1) 318:11	straight (1) 244:16	substantiated (1) 278:16
simplistic (3) 226:8,9 244:24	solid (1) 313:21	stand (1) 272:6	straightforward (1) 244:18	substitute (1) 269:18
simplistically (1) 242:17	somewhat (2) 233:11 313:8	standard (3) 252:18,25 254:11	strategies (1) 298:3	substituted (1) 269:24
simply (15) 220:13 245:5 268:22 268:22 273:22 278:4 281:10 286:5 286:9,12 296:12,14 310:15 317:4 318:6	sorry (22) 220:15 230:2 239:25 246:22 255:18 256:23 257:22 260:22 261:7 263:12 269:22	stands (3) 246:7,10,20	stratify (1) 317:9	substituting (2) 269:22 275:17
simulation (2) 304:2,3	272:25 273:20 274:13 290:6	started (2) 219:23 319:9	Street (4) 212:12 213:5,11 218:12	subverted (1) 313:11
single (3) 251:21 259:18 313:3	291:15 293:8,16 298:2 299:22	starting (1) 242:22	strength (3) 228:1 243:16,21	sufficient (2) 285:5,14
sit (1) 246:13	309:22 315:22	starts (1) 236:20	strengths (2) 233:8 241:11	sufficiently (1) 299:15
site (11) 215:5 232:10 252:10 270:15 287:5 288:5 288:9,19 292:20 299:9 312:4	sort (8) 225:14 226:14 284:22 295:9 317:5,8 318:5 319:11	state (7) 219:9 276:25 286:8 321:1,5 323:3,23	strike (6) 221:6 231:8 232:11 271:5 306:21 307:17	suggest (4) 254:23 268:15 280:11 318:14
sites (5) 291:4 292:1,6,12,22	sorts (1) 307:20	stated (5) 246:15 248:1 268:24 269:13 271:18	strong (5) 226:14 243:22 247:3 272:7 313:10	suggesting (5) 265:25 267:19 279:23 288:1 319:7
sitting (3) 291:21 301:4 319:20	Soto (2) 212:12 218:12	statement (5) 228:25 229:1 230:10 241:24 242:2	studies (20) 225:11 226:11 228:20 229:9 241:4 242:9,9 275:21 284:8	suggestion (3) 245:6 302:19 308:10
six (7) 248:7,19 249:18,20 249:25 260:5 263:23	source (1) 299:7	statements (1) 225:13	studies (20) 225:11 226:11 228:20 229:9 241:4 242:9,9 275:21 284:8	suggests (1) 245:11
sixty (4) 248:17 250:7 262:8 262:12	sources (3) 229:9,20 230:7	States (3) 211:1 212:1 218:9	strong (5) 226:14 243:22 247:3 272:7 313:10	supplemental (1) 277:6
sixty-day (4) 248:5 262:24 263:21 266:10	South (2) 213:5,11	stating (1) 267:20	studies (20) 225:11 226:11 228:20 229:9 241:4 242:9,9 275:21 284:8	supplies (1) 282:16
size (9) 275:23 276:9 291:5 291:12,16,22,23 292:3 294:23	sparse (1) 294:22	statistic (1) 265:25	strong (5) 226:14 243:22 247:3 272:7 313:10	support (4) 271:14 276:17,23 295:24
skimmed (1) 236:2	speaks (1) 266:4	statistical (1) 259:7	study (26) 215:14 225:2 233:3,9 234:13 236:22	supported (2) 285:4 289:1
skin (2) 302:16,25	specialist (1) 218:17	statistically (11) 234:25 235:1 247:5	study (26) 215:14 225:2 233:3,9 234:13 236:22	supporting (1) 288:21
skip (3) 253:12 268:16,16	specific (5) 233:1 239:11 245:12 245:25 259:4	status (1) 267:19 270:20	subject (2) 225:16 271:20	supports (2) 288:12,22
slide (2) 252:8 254:19	specifically (12) 223:10 227:8 234:9 242:6 243:5 251:2	stenograph (1) 275:11 276:4 291:8	subpoena (4) 251:24 256:15 259:20 305:14	suppressed (2) 306:13,15
slides (1) 260:14	specifics (1) 237:14	step (1) 223:24	subscribed (2) 321:10 322:22	suppressing (1) 306:24
slight (1)	specified (2) 251:11 262:18	steps (2) 239:22 240:13	subsequent (1) 229:24	sure (23) 221:20 231:16 243:18 244:11,20 257:9
	spend (3) 221:14 243:25 267:7	sterile (3) 301:17,18 303:14		

surgeon (10) 235:12,18,22 236:6 237:3,22 247:6,11 302:13,16 surgeon's (1) 237:22 surgeon-specific (6) 236:15 238:21,23 243:14,19 247:13 surgeons (1) 237:25 surgeries (2) 299:11,18 surgery (7) 215:16 216:11,22 232:21 286:2,6 311:8 surgical (20) 232:10 235:15 239:7 253:17 270:15 286:17 287:4,8 288:5,9,19 291:4,25 292:6,12,20,20,21 299:9 312:4 surprise (8) 258:14,24 259:13,14 305:18,19 310:6,12 surprised (1) 310:20 surprises (1) 310:16 surrogate (7) 288:18 289:19,24 296:4,5 297:16 298:14 surrogates (1) 298:6 surveillance (3) 317:15 318:7 319:8 suspect (1) 304:17 swear (1) 219:4 switched (3) 248:6 253:9 265:13 switching (3) 250:7 266:2 268:3 sworn (2) 245:8 322:22 synergism (1) 235:19 system (4) 232:3,9 317:15 319:8 systematic (1) 298:16	T T (5) 214:2,13 215:3 216:3 217:3 table (11) 235:20 249:8,12 255:8,14 257:11,14 261:1 269:12 272:22 275:18 tables (1) 255:16 take (15) 237:20 239:22 240:13 249:2 256:4 270:9 270:10 275:7 281:19 300:11,16 313:23 314:6 317:17,18 taken (4) 212:11 281:24 314:2 323:9 talk (2) 223:25 284:20 talked (4) 222:12 304:13 313:14 318:8 talking (10) 227:5 231:21 241:22 282:25 283:1 285:10 287:17 292:7,23,25 talks (1) 250:20 tape (1) 218:6 techniques (1) 290:21 tee (2) 225:19,20 tell (5) 230:24 269:16 270:19 275:9 304:24 telling (1) 281:2 temporal (3) 231:17 233:9 247:19 tend (1) 270:12 term (1) 250:19 terms (2) 299:13 304:2 testified (5) 219:18 221:16 279:6 315:6 317:1 testifying (1)	316:9 testimony (10) 219:10 223:12 230:22 231:24 242:1 244:3 245:1,8,18 316:6 text (4) 253:3 285:3 286:8 294:13 thank (5) 219:3 235:25 314:10 318:20 319:22 Thanks (1) 314:12 theater (1) 303:2 theaters (3) 215:20 232:4 294:16 theatres (1) 216:6 thereof (1) 323:19 thing (4) 219:25 255:11 279:14 299:12 things (18) 224:15 225:5 232:4 232:17,22 236:19 236:23 253:16 257:8 271:11 282:6 283:3 293:21 308:17 312:1 314:6 316:14,14 think (56) 221:16,23 227:20,25 230:11 231:12 232:15 233:8 237:11,13,18,18 242:2 243:15 244:16,18 246:18 246:19 247:17 252:7 260:11 267:15 268:11 269:21 271:17,23 272:5 274:13 275:16 276:23 278:2 280:24 282:12 283:25 284:13,25 285:1 288:2,11,20 289:15 290:22 292:17 296:5 297:13,18 300:5 306:15 307:3 308:4,23 312:24 313:4,9 315:23 319:15 thorough (1)	298:12 three (6) 253:11 254:1 256:1,5 275:21 285:21 thromboprophylaxi... 243:11 time (39) 220:19 221:14 222:23 231:18,20 232:25 233:10 234:13 237:13,20 243:11 243:16,25,25 247:19 251:15 256:4 263:23 264:12 267:8 270:10 281:22 282:1,15 293:18 299:15 300:16,16 305:13 313:25 314:4,6,8 317:2,7,9 317:12 318:7 320:3 times (5) 275:5 276:14 280:18 280:20 311:11 timing (1) 319:18 title (1) 259:21 tobacco (9) 280:17,23 281:9 306:12,23,25 307:1 307:4,4 today (10) 218:24 219:1 221:25 246:5,14 251:16 276:15 291:21 299:5 300:17 today's (1) 320:2 top (1) 258:3 topic (1) 298:16 total (31) 214:23 215:11 235:14 239:8 249:15,20 251:9 252:16,23 253:23 254:20 255:3,12,14 258:6 259:22 261:5,9 262:14 272:13,14 272:15,16,21 273:1 273:2,12,15,18 274:4 284:4 touches (1) 302:16	toxicity (1) 307:7 training (1) 224:12 transcribed (1) 323:10 transcript (2) 321:9 323:13 transition (5) 233:11 262:13 263:22 264:14 265:4 transitioned (1) 253:25 translates (1) 279:8 trend (2) 317:2,12 trial (1) 216:12 tried (1) 305:20 tries (1) 242:11 triple (1) 246:22 tripling (1) 246:22 troubled (3) 280:16,21 306:11 troublesome (1) 309:4 troubling (1) 308:20 true (7) 271:11 278:10 281:2 281:3 312:12 318:14 321:9 truth (3) 219:11,12,12 try (2) 224:18 225:2 trying (3) 237:13 238:13 281:5 TSG (2) 218:15,19 Tuesday (4) 211:15 212:14 218:1 218:13 turn (6) 240:20 257:10,19 286:13 301:22 310:22 turned (2) 293:14 311:25 turning (9) 240:4,22 249:4
--	--	---	---	--

257:12 263:7 301:25 302:20 310:23 315:24 turns (1) 308:16 twenty-four (3) 248:7,19 263:23 two (26) 227:19,24 232:25 233:6,10,12 238:7 238:12 247:19 249:15 261:11,12 261:15 262:14 269:8 282:6 283:3 285:19 286:14,24 287:2,9 294:23 304:10 315:1 318:5 two-month (1) 250:3 typewriting (1) 323:11 typically (2) 277:5 310:17 typing (1) 290:8	305:17 unfair (1) 237:11 unfavorable (2) 306:13,24 Unfortunately (1) 313:17 unidirectional (4) 286:15 287:2,7 288:13 uninformative (1) 296:11 United (3) 211:1 212:1 218:9 units (5) 290:14,16 297:17 298:7 299:19 unknown (1) 231:15 unsafe (1) 307:23 unusual (1) 234:19 use (10) 231:5 259:14 263:16 266:14 282:18 283:25 284:15 286:5 301:9 315:14 useless (1) 296:4 usual (1) 259:15 usually (1) 245:12	274:11 299:9,19 319:19 viable (3) 287:17 290:19 298:6 301:11 302:13 303:5 video (1) 218:16 Videographer (8) 213:15 218:5 219:3 281:22,25 313:25 314:3 320:1 videotaped (3) 211:13 212:10 218:6 view (4) 226:15 262:20 284:23 295:24 Volume (2) 211:5 214:16	265:19 266:10 268:9 269:11 270:13 275:4 276:4 281:6 282:18 293:15 300:2 301:9 wash-out (6) 248:5 250:3 262:8,24 263:21 266:10 wasn't (1) 316:10 waste (1) 254:6 way (17) 235:1 236:13 237:23 241:4 242:12 246:25 259:15 277:9 281:6,8,8 283:13,16 286:20 287:10 306:12 323:19 ways (3) 227:24 242:10 305:20 we'll (8) 223:15,15,25 225:20 230:5 285:20 305:1 319:25 weaknesses (1) 241:12 website (1) 312:7 weighing (1) 241:8 well-conducted (1) 316:10 well-known (1) 228:19 well-qualified (1) 234:6 well-respected (1) 304:15 went (4) 243:24 265:12 266:1 271:18 Wenzel (1) 221:17 weren't (3) 220:11,11 290:8 WHEREOF (1) 321:10 William (1) 233:17 window (2) 314:8 319:19 withdraw (1) 256:3 witness (71)	219:5,8,13 230:2 235:7,8 238:4 239:1 240:4,5,22 241:20 245:22,25 247:17 249:4 250:17,18 254:18 255:2 257:12,24 263:7 264:5 265:1,17 266:20 268:7 271:16,21 273:6 274:23 275:15 276:8 277:15 280:10 281:20 283:10 285:14 292:16,17 293:5,6 294:7,20,21 295:16 297:8 299:24,25 301:25 306:1 308:4 308:23 309:6 310:14,23 312:21 314:9,10,21 315:4,9 315:24,25 316:18 316:20 317:22 318:18 321:10 323:5 word (3) 259:14 284:1,16 words (4) 229:18 235:19 236:18 294:14 work (4) 306:19 307:3 309:8 313:10 worked (1) 224:15 world (2) 254:10 282:23 wouldn't (10) 237:5,9 242:16 277:9 278:5,5 283:25 284:17,19 288:9 wound (5) 214:23 235:15 239:7 254:6 318:10 writing (1) 323:10 written (2) 226:13 228:11 wrong (7) 223:16 226:18 231:24 255:19,19,20 278:13 wrote (2) 226:7 278:18
U	V			X
ultimate (1) 287:9 uncertainty (2) 277:1 278:20 uncontrolled (1) 247:2 underestimated (1) 317:25 underlies (1) 284:15 underlying (1) 290:10 understand (14) 228:10,11 236:1 237:4 238:10,14 264:8 270:5 271:22 274:6 300:12 310:9 314:7 317:12 understanding (8) 223:1 224:14 249:1 249:22 250:14 262:9 291:17 304:14 understood (5) 248:14,24 251:16 270:22 307:4 undertaken (1) 297:19 undertook (1)				

X (11)	1	155 (1)	255:12 261:5,8,21	24 (7)
214:1,13 215:1,3	1 (45)	273:18	261:22 265:22	215:8 255:18 256:7,8
216:1,3 217:1,3	217:5 218:6 220:22	16 (3)	267:1,3,11,17 270:1	256:11 257:10,20
235:12 236:5	221:2 248:21 249:6	171 (2)	274:11,17 280:2,4	25 (21)
323:13	249:8 253:18 255:8	272:16,18	305:13 317:16	215:11 259:17,24
Y	255:8,14,15 257:11	18- (1)	319:3,4,8,16	260:20 261:4,6,9,13
y (1)	257:14,15 261:1	240:3	2009 (18)	261:14,20 263:6
281:1	262:1,10 263:4	1810 (1)	215:12 226:4 252:24	264:17 266:17
yeah (16)	268:1,20,22 269:3,9	240:7	254:3 255:12	268:19 269:1,19,25
224:25 226:4 232:15	269:12,20,24	1812 (1)	259:22 261:5,9,21	271:2 273:14
245:22 246:22	270:24 271:9,25	240:21	261:22 267:5,6,11	276:21 277:16
258:2 259:1 260:15	272:22,22 273:11	1989 (1)	267:17 271:9	252 (1)
266:5,25 276:8	273:22 274:4,24	233:15	274:11,18 280:2	215:5
279:13 280:19	275:3,19,24,25	1990 (1)	2011 (1)	256 (1)
281:20 290:12	276:10,22 278:9	233:16	311:7	215:8
301:6	281:13 285:24	1.0 (1)	2012 (1)	259 (1)
year (19)		276:1	294:2	215:11
248:2,16 249:25	1.04 (1)	2 (8)	2015 (1)	26 (7)
262:7,12 263:9	265:20	272:6,12,14 275:10	215:10	215:13 289:6,8,15,18
264:6,13 265:6	1.1 (1)	275:24 276:11	2016 (1)	289:23 291:6
266:9,10 267:1	265:21	285:24 286:2	314:25	27 (5)
268:9,16,24 269:11	1.33 (1)	2.8 (2)	2017 (11)	215:18 293:22,24
270:1,2,2	265:21	246:19,24	211:15 212:14 214:15	294:5,11
years (5)	1.5 (1)	2.86 (4)	217:6 218:1,13	28 (4)
253:11 254:1 261:12	262:11	244:7,15 245:20	298:20 321:5,11	216:5 296:20,23
262:3 268:21	1.55 (3)	246:2	322:23 323:20	297:23
Z	252:17 253:24 260:5	20 (7)	2080 (1)	289 (1)
zero (1)	10-micron (1)	214:15 222:14,16	257:23	215:13
263:12	291:9	223:9 247:23,25	2086 (1)	29 (5)
zone (1)	10:07 (1)	269:12	256:9	216:9 264:2,23
302:15	10:53 (1)	200- (2)	2094 (2)	298:20,23
zones (2)	313:25	226:1,4	219:17 323:8	29-page (1)
301:14 303:11	10:56 (1)	2000 (1)	21 (5)	293 (1)
0	314:4	271:9	214:19 225:19,22	306:2
0 (2)	11 (4)	2001 (2)	228:4 239:13	215:18
264:1,22	220:2 222:5,24 223:4	212:12 218:12	211-324 (1)	296 (1)
0.29 (3)	11:01 (2)	2005 (1)	211:5	216:5
252:24 254:2 261:16	320:3,6	296:21	272:16,18	216:9
0.8 (1)	11th (1)	2006 (15)	219 (1)	2B (2)
254:10	323:20	215:12 252:17 255:6	214:4	285:19,23
0002079 (1)	12 (1)	259:22 260:4,9,19	22 (6)	3 (10)
256:9	315:17	260:21 265:10,20	214:22 215:10 233:14	234:24 235:12,18,22
05 (1)	12568 (3)	266:14 268:11	233:19 242:7 247:4	236:6 257:10 272:7
226:24	211:25 212:15 323:2	271:7,9 280:3	221 (1)	285:25 286:3,14
07 (1)	128394 (1)	2007 (27)	217:5	3.8 (8)
269:19	211:24	263:9,12,17 264:6,21	222 (1)	243:23 245:15 246:11
08 (1)	13 (2)	265:5,10,20 266:15	214:15	246:17,24 279:7
269:20	315:19,23	267:10,16,18 268:8	225 (2)	311:11,15
09 (1)	14 (2)	268:11,23 269:11	213:5 214:19	3.86 (1)
269:20	285:16 286:13	269:25 271:7,10	23 (9)	246:8
000- (2)	15-2666 (2)	273:15 274:11,17	215:5 251:20 252:2	30 (10)
218:3 320:7	211:4 212:4	280:2,4 305:13	260:11,12,16,17,21	216:14 217:6 221:10
	152666 (1)	317:13,14	261:22	223:19 232:1,12
	218:10	2008 (24)	233 (1)	
		216:18 252:24 254:2	214:22	

300:19,22 302:2 316:2 300 (1) 216:14 305 (1) 216:17 309 (1) 216:20 31 (4) 216:17 305:3,6 316:2 314 (1) 214:5 318 (1) 214:4 32 (4) 216:20 309:10,13 310:22 344 (2) 263:10,12 35 (3) 255:24,24,25 3548 (1) 309:11 3551 (1) 309:11 37 (6) 266:17,22 267:2 270:4 274:17,21 388 (8) 249:20,24 252:18 255:6,9,10 260:5 273:12 393 (2) 272:19 275:10 3M (1) 219:1 3rd (1) 212:12	5-micron (1) 295:7 50,000 (1) 223:25 50,000-foot (1) 284:23 537 (1) 273:16 55 (1) 255:24 55402 (1) 213:6 55415 (1) 213:12	90032 (1) 212:13 929 (3) 272:23 273:4,10 944 (1) 273:4 945 (4) 273:5,6,8,10
	6	
	6 (1) 300:20 67 (1) 265:19 677 (11) 249:16 250:5,14 252:25 255:13,16 74 (2) 279:8,19 76 (2) 267:2,4 777 (1) 261:6,9,12,15 78 (2) 262:14 6th (1) 213:5	
	7	
	74 (2) 279:8,19 76 (2) 267:2,4 777 (1) 261:6 78 (2) 261:6 79 (1) 279:3,19	
	8	
	8 (8) 211:15 212:14 218:1 218:13 285:11,19 305:4 321:5 8:36 (3) 212:14 218:2,14 80 (1) 254:9	
	9	
	9 (6) 226:2,4 265:22 270:1 280:4 298:4 9:58 (1) 281:22 9:6998 (1) 214:16	
	5	
5 (3) 294:25,25 295:6		